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(54) Title: APPARATUS AND METHODS FOR CLOSING SEPTAL DEFECTS AND OCCLUDING BLOOD FLOW			
(57) Abstract			
<p>Plugs and methods for plugging septal defects and blood vessels are provided. Plugs are delivered via catheter to a septal defect or a location where it is desired to occlude blood flow in a blood vessel. The plugs are positioned and expanded at the treatment site. The expansion of the plugs can be accomplished passively by using a heat-treated elastic frame or actively by using a balloon to deform a plastically-deforming frame. Plugging structures mounted to the frame span the defect or lumen and prevent blood flow. The plugs described herein have small profiles, and are more reliable than preceding intraluminal transcatheter methods.</p>			

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Description

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APPARATUS AND METHODS
FOR CLOSING SEPTAL DEFECTS
AND OCCLUDING BLOOD FLOW

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Background of the Invention

5 This invention relates to apparatus and
methods for closing intravascular defects and occluding
25 blood flow. In particular, it relates to closing
septal defects or holes found between the walls of the
four heart chambers and occluding blood flow in
10 sections of a patient's circulatory system.

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 The heart chambers include left and right
atrial chambers in the upper portion and left and right
ventricular chambers in the lower portion. Defects in
these walls can be formed congenitally or can develop
15 later in life. An atrial septal defect (hereinafter,
35 "ASD") is found between the right and left atrium and a
ventricular septal defect (hereinafter, "VSD") is found
between the left and right ventricles. The defect
allows blood to be shunted between the chambers,
40 causing the heart's pumping action to be inefficient,
20 and creating a

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5 risk of embolization (the circulation of an abnormal particle through the bloodstream).

10 A similar defect is the patent ductus. The patent ductus is a pre-birth opening between the aorta and the pulmonary artery. This opening usually closes naturally, but may remain open and cause oxygenated blood to flow back into the lungs. Another defects are the ductus arteriosus and the patent foramen ovale (hereinafter, "PFO"). At least fifty percent of stroke patients under 55 years old have a PFO.

15 Therapeutic treatment of these defects normally requires extensive surgery. For example, treatment typically requires open heart surgery, cardiopulmonary bypass, and stopping of the heart. During treatment, the defect is sewn shut by applying a thin patch over the hole. Less invasive methods for closure of these defects, such as intraluminal transcatheter approaches, for example, but provide unreliable delivery and deployment. A transcatheter apparatus has a large delivery profile that limits application of the method to young patients and makes it difficult to match the apparatus to the intracardiac or extracardiac cavity and can result in thrombosis, emboli, or dislodgement due to interference with blood flow.

25 It is also known that septal holes cause strokes by shunting clots from the right atrium to the left atrium. From the left atrium, a clot can go to the brain. Some holes are asymptomatic and should still be closed to prevent future stroke. Patients having asymptomatic defects would benefit from a low-invasive and reliable treatment apparatus and method.

30 In addition to the treatment of septal defects, it is often desirable to occlude blood flow in a section of the circulatory system. Occlusion can control internal bleeding and buffer pressure in the vicinity of an aneurysm.

35 Therefore, it would be desirable to provide apparatus and methods for treating septal defects, such

5 as ASD, VSD, and PFO, that function at least as well as
the proven surgical thin sewn patch, but which are less
invasive.

10 5 It would also be desirable to provide reliable
apparatus and methods for delivery of intraluminal
transcatheters and deployment of septal defect devices
and plugs.

15 10 It would be more desirable to provide these
apparatus and methods such that the delivery profile is
small and such that they can be used to treat patients of
a wide range of ages.

20 15 It would be further desirable to provide septal
defect devices and occluding plugs that can be properly
matched to the intracardiac or extracardiac cavity.

25 20 It would be still further desirable to provide
apparatus and methods for percutaneous delivery and
deployment of occlusion devices for blocking blood flow
in various sections of the circulatory system.

Summary of the Invention

30 20 Therefore, it is an object of the invention to
provide apparatus and methods for treating septal
defects, such as ASD, VSD, and PFO, that function as well
as the proven surgical thin sewn patch, but which are
less invasive.

35 25 It is also an object of the invention to
provide reliable apparatus and methods for delivery of
intraluminal transcatheters and deployment of septal
defect devices and plugs.

40 30 Additionally, it is an object of the invention
to provide these apparatus and methods such that the
delivery profile is small and such that they can be used
to treat patients of having a wide range of ages.

45 35 It is a further object of the invention to
provide septal defect devices and occluding plugs that
can be properly matched to the intracardiac or
extracardiac cavity.

5 It is a still further object of the invention
to provide apparatus and methods for percutaneous
delivery and deployment of occlusion devices for blocking
blood flow in various sections of the circulatory system.

10 5 In accordance with one aspect of the present
invention, a plug is provided for closing an aperture in
a wall of a patient's body cavity. The plug includes: a
frame that has a central axis; a first plurality of
15 10 fingers configured to engage an interior surface of the
body cavity wall; a second plurality of fingers that are
attached to the first plurality and are configured to
engage an exterior surface of the body cavity wall; and a
plugging structure. The fingers can be positioned
20 substantially circumferentially about the central axis.
15 The plugging structure is attached to the frame and spans
the aperture when the plug is in position. Furthermore,
cross-sections of the frame that lie in a plane
25 substantially perpendicular to the central axis are
substantially discontinuous in order to enable the plug,
20 and particularly the frame, to conform to the perimeter,
or contour, of the aperture.

30 According to another aspect of the invention, a
plug is provided that has a perforated tubular portion
having a longitudinal passage. Any cross-section of the
25 perforated tubular portion taken along a plane
35 perpendicular to the passage is substantially
discontinuous to allow conformation of the portion to
perimeter of the aperture. The plug has a plurality of
fingers extending from each of the two axial ends of the
40 30 perforated tubular portion. Preferably, any cross-
section of the fingers taken along a plane perpendicular
to the passage is also substantially discontinuous. The
plug also has a plugging structure as described above.

45 In yet another aspect of the invention, an
35 occlusive device is provided for occluding blood flow at
a treatment site. This device is similar to the
preceding plugs, but has fingers extending from only one
50 axial end of the perforated tubular portion. During

5 operation, these fingers anchor the device to the
internal surface of a blood vessel.

According to still another aspect of the
invention, methods for plugging an aperture in a wall of
10 a patient's body cavity is provided. The method includes
positioning a conformable plug in the aperture,
conforming the plug to the aperture, and securing the
plug in the aperture. It will be appreciated that the
15 steps of conforming and securing could occur at the same
time. Methods for occluding blood flow are also
provided.

Brief Description of the Drawings

20 The above and other objects and advantages of
the invention will be apparent upon consideration of the
following detailed description, taken in conjunction with
15 the accompanying drawings, in which like reference
characters refer to like parts throughout, and in which:

FIG. 1 is a plan view of a plug for plugging a
septal defect in accordance with this invention;

20 FIG. 1A is a partial side elevational view
along direction 1A-1A of FIG. 1 in accordance with the
principles of this invention;

FIG. 2 is a side elevational view of a finger
of a plug in accordance with this invention;

35 FIG. 3 is a side elevational view of another
finger of a plug in accordance with this invention;

FIG. 4 is a side elevational view of yet
another finger of a plug in accordance with this
40 invention;

30 FIG. 5 is a side elevational view of still
another finger of a plug in accordance with this
invention;

45 FIG. 6 is a plan view of another plug for
plugging a septal defect in accordance with this
35 invention;

FIG. 7 is a side elevational view of yet another finger of a plug in accordance with this invention;

FIG. 8 is a plan view of yet another plug for plugging a septal defect in accordance with this invention;

FIG. 9 is a plan view of yet another plug for plugging a septal defect in accordance with this invention;

FIG. 10 is a cross-sectional view of a plug for plugging a septal defect disposed within a delivery device in accordance with this invention;

FIG. 11 is a cross-sectional view of the plug shown in FIG. 10 when the plug is partially deployed in the septal defect in accordance with this invention;

FIG. 12 is a cross-sectional view of the plug shown in FIG. 10 and 11 when the plug is fully deployed in the septal defect in accordance with this invention;

FIG. 13 is a cross-sectional view of a plug similar to the one shown in FIGS. 10-12 when the plug is fully deployed showing the delivery path of a delivery device in accordance with this invention;

FIG. 14 is a cross-sectional view of the plug shown in FIG. 13 for plugging a septal defect when the plug is fully deployed and the delivery device has been retracted from the heart in accordance with this invention;

FIG. 15 is an elevational view of the plug shown in FIGS. 13 and 14 taken along line 15-15 of FIG. 14 in accordance with this invention;

FIG. 16 is a plan view of yet another plug for plugging a septal defect in accordance with this invention;

FIG. 17 is a plan view of the plug shown in FIG. 16 from the opposite side in accordance with this invention;

FIG. 18 is a cross-sectional view of the plug shown in FIGS. 16 and 17 when the plug is fully deployed in the septal defect in accordance with this invention;

FIG. 19 is a plan view of the plug shown in FIGS. 16-18 taken from line 19-19 of FIG. 18 in accordance with this invention;

FIG. 20 is a partial elevational view of an unrolled frame for an illustrative plug in accordance with this invention;

FIG. 21 is a perspective view of the frame shown in FIG. 21 with ends attached (showing only a single finger at each axial end of the frame) in accordance with this invention;

FIG. 22 is a cross-sectional view of the frame shown in FIGS. 20 and 21 with ends attached in accordance with this invention;

FIG. 23 is an elevational view of the frame shown in FIG. 22 in accordance with this invention;

FIG. 24 is a perspective view of the frame shown in FIG. 21 with an attached plugging structure to form a plug in accordance with this invention;

FIG. 25 is an elevational view of the plug shown in FIG. 24 (showing a number of forward facing fingers) after the fingers have been bent into the wall-engaging position in accordance with this invention;

FIG. 26 is a partial elevational view of an unrolled frame with a plugging structure in accordance with this invention;

FIG. 27 is an elevational view of another unrolled frame for a plug in accordance with this invention;

FIG. 28 is an elevational view of another plug mounted on a delivery balloon in accordance with this invention;

FIG. 29 is a cross-sectional view taken of the plug shown in FIG. 28 in position for deployment in a defect in accordance with this invention;

FIG. 30 is a cross-sectional view of the plug shown in FIGS. 28 and 29 when the plug is deployed in the defect in accordance with this invention;

FIG. 31 is a cross-sectional view of the plug shown in FIGS. 28-30 in position for deployment showing the delivery path of a delivery device in accordance with this invention;

FIG. 32 is a cross-sectional view of yet another plug for plugging a septal defect when the plug is fully deployed in the septal defect in accordance with this invention;

FIG. 33 is a partial elevational view of an unrolled frame for an occlusion device (i.e., a plug) in accordance with this invention;

FIG. 34 is an elevational view of another occlusion device with barbs mounted on a delivery balloon in accordance with this invention;

FIG. 35 is a partial elevational view of another occlusion device for occluding a section of a blood vessel in accordance with this invention; and

FIG. 36 is a cross-sectional view of the occlusion device shown in FIG. 35 deployed in a blood vessel in accordance with this invention.

Detailed Description of the Preferred Embodiments

The invention provides apparatus and methods for preventing the flow of body fluids through apertures in body cavity walls and through a patient's body tubing, such as a blood vessel. The apparatus can be a plug that is installed in the patient's body using an intraluminal catheter method. The plug can have a (1) frame that conforms to the walls of an aperture (e.g., a defect) or a section of tubing and (2) a plugging structure (e.g., a patch) that prevents the flow of fluid. Although the plug can be installed in a variety of types of body tissues to prevent the flow of body fluid, only embodiments of the invention related to preventing the

5 flow of blood through passageways in the circulatory system will be illustrated herein.

10 In one embodiment, a plug is provided for closing an aperture or hole in a septal wall of a patient's heart, for example a PFO. The plug has a frame, two pluralities of fingers attached to axial ends of the frame and to each other, and a plugging structure attached thereto. The pluralities of fingers can be integral with the frame and formed from a unitary body.
15 During operation, one plurality of fingers engages an interior surface of the wall and the other set of fingers engages the opposite, or exterior, surface. The plugging structure is supported by the frame and spans the aperture (e.g., defect) to prevent the flow of blood
20 there through.

25 The fingers are preferably positioned substantially circumferentially (i.e., peripherally) about the plug's central axis, which passes through the frame. The fingers can extend radially away or along the axis. The fingers have ends that are radially proximal to the central axis and which generally define a
30 substantially round or elliptical broken cross-section in a plane substantially perpendicular to the central axis.

35 Preferably, any cross section of the frame that lies in a plane substantially perpendicular to the axis is substantially discontinuous. This allows the frame to contract and expand radially as necessary for insertion into a delivery device, placement in an aperture, and conformation to the walls of the aperture. The frame
40 itself can comprise an elastic material, such as nitinol. Alternatively, the frame can comprise a plastically deforming material, such as stainless steel. The elastic and plastic embodiments may be delivered differently.

45 When the plug is inside the patient's body, medical scanners can be used to assist and confirm plug placement and to evaluate the integrity of a plug after it has been in use for an extended period of time. The
50 frame may be equipped with one or more marker structures.

5 which can be radiopaque, to help identify, locate, and
orient the plug using images produced with, for example,
X-rays, CT scans, ultrasound, and echo techniques

10 Marker structures can be provided in a variety
5 of forms. For example, a marker structure can be in the
form of a marker band made from a radiopaque material
that is crimped onto an end portion of a finger.
Alternatively, a marker structure can be a rivet that is
15 inserted and locked into a ring or hole in a finger. If
10 marker structures are used, they can be provided on any
number of fingers.

20 Other structures can be present on the fingers
of the plug to facilitate its delivery. For example, a
finger can be provided with a retention device
15 receptacle. A retention device reciprocates within a
delivery sleeve or catheter and engages the fingers while
the plug is inserted in the delivery sleeve so that the
25 plug can be reciprocated within the sleeve and shifted
into position in the aperture, such as a PFO. Once in
20 position, the retention device can release the fingers so
that the fingers spring into engagement with the aperture
30 wall.

In one embodiment, the frame of the plug is
insertable into a delivery tube by extending the fingers
25 in a direction substantially parallel to the central
axis. The retention device itself has fingers or locking
pins that engage the retention device receptacles that
reside on the ends of the frame fingers. Retention
device receptacle include, but are not limited to,
40 locking pin apertures and nose cone covers.

Fingers may have a variety of designs that are
tailored to optimize plug security for the shape and
tissue characteristics of a given PFO. For example,
45 fingers can have pointed ends, barbs, or curved portions.
35 In one embodiment, fingers can be curved toward a plane
that is perpendicular to the central axis and that passes
substantially between the two pluralities of fingers.
50 Fingers can be of substantially similar length or

5 substantially different lengths. Any finger can have
different flexural stiffness at different points along
its length. One way to accomplish differential flexural
stiffness of a finger is to provide a finger having a
10 5 different thickness or a different width at different
points along its length. Alternatively, both the finger
thickness and the finger width can vary along the length
of a given finger, if desired.

15 In certain cases, the force applied by a finger
10 to the septum wall can be distributed to minimize stress
concentration in the wall. In that case, the plug can be
provided with an elastic web supported between adjacent
fingers. The web, for example, can include silicone.

20 The plugging structure that occludes the PFO
15 can be attached to or supported by the frame at proximal
or distal ends of the fingers. In either case, the
fingers' ends can be provided with support structures
25 with which the plugging structure can be affixed.

30 In one embodiment, the plugging structure is
20 made from an elastic material and can contract and expand
as the frame contracts and expands (e.g., during delivery
and deployment). One material that can be used to make
the plugging structure is polyester (such as the material
sold under the trademark DACRON® by E.I. du Pont de
25 Nemours & Company of Wilmington, Delaware.).

35 The plugging structure can also be made from
cloth and be folded and unfolded as the plug is
contracted and expanded as may be necessary for its
installation in the defect. In either the elastic or
40 30 cloth embodiments of the plugging structure, the plugging
structure can be attached (e.g., sewn) directly to the
frame. The plugging structure can have a guide wire
aperture through which a guide wire can pass. If the
45 guide wire is inserted into the patient prior to plug
35 delivery, the guide wire can be used to guide the plug
into place in the PFO. The guide wire aperture can be
designed to substantially self close after the guide wire
is removed from the guide wire aperture. The self-

5 closing feature can be achieved by making the diameter of
a guide wire aperture in the relaxed state (i.e., without
the wire) small enough to induce clotting and close off
blood flow.

10 5 In another embodiment, the plug has a
perforated tubular portion that forms a longitudinal
passage. Fingers extend from each of the two axial ends
of the perforated tubular portion and may be provided in
15 a variety of configurations and made from a variety of
materials. Any of the features discussed above may also
be included. Like the frames discussed above, the
perforated tubular portion is discontinuous along any
20 cross section taken in a plane perpendicular to its
longitudinal axis. This feature permits the perforated
15 tubular portion to contract and expand radially and
longitudinally for delivery, deployment, and conformation
to the walls adjacent a PFO, for example. Similarly, the
25 plurality of fingers may be discontinuous along a cross
section taken in a plane perpendicular to the
20 longitudinal axis to allow such contraction and expansion
as well.

30 The plugging structure can be supported
directly or indirectly by the perforated tubular portion.
For example, the plugging structure can be attached
25 directly to the perforated tubular portion or to elements
of the structure (such as tabs, bosses, extensions, or
35 loops). Alternatively, the plugging structure can be
attached via interceding support structures (such as
attachment rings, clips, or loops) that connect the
40 tubular portion to the plugging structure.

45 The perforated tubular portion preferably
contracts longitudinally as it expands radially. The
tubular portion can be made of a material that deforms
plastically or elastically. A plastically deforming
35 material can be, for example, stainless steel or
tantalum. The plug is installed by positioning the plug
in the aperture of the PFO and expanding a balloon inside
the plug to at least partially conform the perforated
50

5 tubular portion to the perimeter of the aperture. The
perforations allow the plug to contract longitudinally in
response to the radial expansion. The longitudinal
contraction causes the fingers to engage opposing sides
10 5 of the wall.

10 According to another aspect of the invention,
an occlusion plug is provided. The occlusion plug has a
perforated tubular portion for occluding a blood vessel.
This type of plug may be desirable to prevent blood flow
15 10 near a damaged portion of the vessel (e.g., aneurysm).
The occlusion plug can be plastically or elastically
deformable.

20 In the plastic embodiment, the occlusion plug
is installed in the blood vessel by expanding a balloon
15 15 in a longitudinal passageway of the perforated tubular
portion. The expansion of the balloon causes the plug to
expand radially and contract longitudinally. This
25 25 expansion causes the outer surface of the perforated
tubular portion to conform to the inner surface of the
20 20 lumen of the blood vessel. The expansion also causes the
fingers at the end of the perforated tubular portion to
30 30 engage the inner surface of the wall as they are driven
radially outward from the longitudinal axis and drawn
longitudinally toward the perforated tubular portion.

25 25 The fingers of the occlusion plug preferably
extend from only one axial end of the perforated tubular
35 35 portion. The configuration of the fingers, the
structures associated with the fingers, the perforated
tubular portion, and the relation of the fingers to the
40 40 perforated tubular portion are similar to those described
above in connection with the PFO plug.

45 The invention also includes methods for
preventing the flow of body fluids through apertures in
body cavity walls. For simplicity plugging PFO's alone
45 45 will be discussed. In a preferred embodiment, a plug
that is at least partially made from an elastic material
and is conformable to a defect, such as any of those
50 50 elastic plugs described above having two opposing

5 pluralities of fingers, is positioned at the defect,
conformed to the perimeter of the defect and secured
thereto.

10 In order to position the plug in the PFO, a
5 delivery structure with a sleeve is provided. During the
process of positioning the plug, the plug fingers are
extended in a direction that is substantially parallel to
the central axis of the plug while the plug is inserted
15 into the sleeve of the delivery structure. A retention
device inside the sleeve engages at least some of the
extended fingers at the finger ends. The retention
device can use locking pins, hooks, or any other means to
20 retain the plug inside the sleeve. The retention
elements permit an operator to reciprocate the plug
longitudinally with respect to the sleeve and to shift
15 the plug out from the end of the sleeve. The sleeve can
be inserted like a catheter through an incision aperture
in a patient's body tissue. The sleeve can then be
25 passed through the patient's internal body tubing or
other body structures until the end of the sleeve is
positioned within or adjacent the PFO for plug delivery.

30 Once the end of the sleeve is near or within
the PFO, the delivery structure can be shifted relative
to the plug and the PFO, thereby removing the delivery
25 structure from the PFO. The plug, however, extends
through the PFO and the plug fingers extend outward,
preferably radially, from the central axis of the plug on
opposite sides of the wall in which the PFO resides.
This causes the plug fingers to engage the wall and the
40 plugging structure to substantially occlude the PFO.

45 Preferably, releasing the plug within the PFO
allows the plug to expand elastically inside the PFO
until the plug substantially conforms to the inner rim or
perimeter of the PFO. In one embodiment, the plug is
35 allowed to elastically contract along the central axis of
the plug while it expands radially. This longitudinal
contraction causes the fingers to engage opposite sides
of the same wall of the body cavity. A benefit of this
50

5 approach is that the plug will center itself with respect to the wall in a direction along the plug's central axis (or along the longitudinal passage of the plug).

10 According to another embodiment of the invention, a plastically deformable plug can be inserted in a PFO using a balloon. A conformable plug, such as any of those plastically deformable plugs described above, is positioned in the PFO, conformed to the perimeter of the PFO, and then secured thereto. The 15 positioning can be achieved by inserting a delivery balloon into the tubular portion of the plug and delivering both through a patient's body tissue, (e.g., through an insertion aperture and blood vessels), to the PFO. Then, the balloon, which supports the plug, is 20 moved through the patient's body until the plug is appropriately positioned in the aperture -- such that one plurality of fingers is situated on each side of the wall. 25

The plug conforms to the PFO when the balloon 20 is expanded. This causes the fingers to engage on both sides of the septal wall. The tubular portion of the plug radially enlarges and conforms to the perimeter of the aperture and the plugging structure occludes the aperture. When a plug (such as any of those described 25 above) is used according to this method, the balloon expansion plastically deforms the tubular portion. This expansion automatically causes the tubular portion to contract in the direction parallel to the central axis of the plug. (It will be appreciated that the tubular 30 portion could be annular or have a ring-like arrangement of tabs or other elements). The axial contraction causes the plug to substantially center itself with respect to the wall and drives the fingers into both sides of the wall. 35 40 45

35 A number of embodiments according to the present invention, with several variations, are shown in FIGS. 1-36.

FIG. 1 shows plug 100 for closing an aperture, such as an ASD, a VSD, or a PFO, in a wall of a patient's body cavity. Frame 102 can be made from an elastic material, such as nickel titanium (hereinafter, "nitinol," available, for example, from Shape Memory Applications, of Santa Clara, California). The elastic nature of frame 102 allows frame 102 to radially contract sufficiently to allow it to be inserted into an aperture and subsequently radially expand to conform to the inner perimeter of the aperture. Other elastic materials can also be used to construct the frame and could be used in combination with other non-elastic materials. Radial expandability is facilitated by constructing the frame such that any cross section perpendicular to its central axis is discontinuous.

Frame 102 has central axis 104 and supports plugging structure 106. Frame 102 includes first plurality of fingers 108 and second plurality of fingers 110. In one embodiment, fingers 108 are integral with fingers 110. Fingers 108 and 110 have proximal ends 120 that are near central axis 104 and remote ends 112 that are near the radially outer portions of frame 102.

Proximal ends 120 can be used to support plugging structure 106 directly, or they can be equipped with support structures 130 for supporting plugging structure 106. Alternatively, remote ends 112 can support plugging structure 106. Remote ends 112 can also be equipped with support structures 113 for supporting plugging structure 106, and, as discussed more fully below, marker devices. The ends can also be adapted to engage a retention device during plug installation. In FIG. 1, each support structure 113 has aperture 114 to which a plugging structure can be sewn or otherwise attached.

Plugging structure 106 can be made from an elastic material. Plugging structure 106 can also be folded and unfolded to allow frame 102 to deform during

5 insertion into the aperture. A foldable and unfoldable
plugging structure can be either elastic or non-elastic
and may include a cloth or polymeric material. In one
embodiment, plugging structure 106 is made of polyester.

5 Plugging structure 106 can include guide wire
10 aperture 140 for insertion of a guide wire (not shown)
during installation of the plug in a patient. Guide wire
aperture 140 may be self-closing after the removal of a
15 guide wire. In elastic embodiments, the self closing
10 feature may be effected by the elasticity of plugging
structure 106. In cloth embodiments, which may or may
not be elastic, the woven fibers under tension from
frame 102 can automatically close guide wire
20 aperture 140.

15 Remote ends 112 can also be provided with
retention device receptacles for engaging a retention
device that is part of a system for delivering the plug
25 to an aperture in a wall. Finger aperture 114 can be
used as a retention device receptacle. A nose cone cover
20 (e.g., cover 314, shown in FIG. 3), is an alternative to
a retention device receptacle. The delivery system is
discussed below.

30 As shown in FIG. 1, fingers 108 and 110 can
extend substantially radially away from central axis 104,
25 even though some of those fingers may have tangential or
spiral components and may not conform to a radial
35 pattern. One or more of fingers 108 and 110 may also
contain marker structures, such as a marker band.
FIG. 1A shows a partial side view of plug 100 with
40 fingers 108 and 110 in an intermediate configuration
without plugging structure 106. For illustrative
purposes, only a small number of fingers are shown in
FIG. 1A. In an intermediate configuration, fingers are
45 neither parallel nor perpendicular to central axis 104.
35 As can be seen from FIG. 1A, cross-section 160, which is
perpendicular to central axis 104 and passes through the
medial section of plug 100, is discontinuous.

FIGS. 2-5 show different features that can be incorporated into a finger. FIG. 2, for example, shows a side view of finger 208, having proximal end 220 and remote end 212, with rivet 214 mounted thereto. Rivet 214 can be mounted on a finger such that the rivet head engages the patient's heart wall or such that they face toward the heart cavity. FIG. 3 shows finger 308, having proximal end 320 and distal end 312, with nose cone cover 314. FIG. 4 shows finger 408, having proximal end 420 and distal end 412, with barb 414. FIG. 5 shows finger 508 which is curved. If a plug has two sets of fingers (as shown in FIG. 1), the fingers of each set may be curved toward each other.

FIG. 6 shows another embodiment of a plug constructed in accordance with this invention in which proximal ends 620 of fingers 608 and 610 define substantially elliptical cross section 650. Elliptical cross section 650 is in contrast to round cross-section 150 shown in FIG. 1. As shown in FIG. 6, central axis 604 passes near the center point of the ellipse. plugging structure 606, which is supported by proximal ends 620, has a substantially elliptical shape and could have a guide wire aperture (not shown), if desired.

FIG. 7 shows an example of finger 708, which has proximal end 720 and distal end 712. Finger 708 tapers from thickness t_1 at proximal end 720 to lesser thickness t_2 at end 712 (e.g., remote from the plug's central axis). Conversely, finger 708 may be thicker at the remote end and thinner at the proximal end. Thus, a finger, such as finger 708, can have a resulting flexural stiffness that varies along its length. Fingers of varying width, such as the fingers shown in FIG. 1, can also have flexural stiffnesses that vary along their lengths regardless of variations in thickness by varying composition along the length.

FIG. 8 shows another illustrative embodiment of a plug constructed according to this invention in which fingers 808 and 810 have lengths that vary with respect

5 to each other. Although fingers 808 and 810 have
different lengths, it will be appreciated that plugging
structure 806 can have a substantially circular, or any
other convenient, shape.

10 5 FIG. 9 shows another alternative embodiment of
a plug constructed according to this invention in which
elastic web 907 spans between adjacent fingers of a
plurality of fingers 908. The web can be made from any
elastic material, including silicone. Plugging
15 10 structure 906 is supported by proximal ends of
fingers 908 and 910, and can be supported by support
structures 930.

20 FIG. 10 shows how a plug, such as plug 100, can
be installed via a delivery device, such as delivery
15 catheter 1090. Plug 100 is inserted into delivery
catheter 1090 by orienting fingers 108 and 110 in a
direction that is substantially parallel to central
25 axis 104. Next, plug 100 is passed through to distal
opening 1010. Optional marker rivets 114 are shown in
20 FIG. 10. Although it will be appreciated that plugging
structure 1006 can be any convenient type, plugging
structure 1006 is shown as a folded plugging structure.
Retention device receptacles 1016 are engaged with
locking pins 1022 of retention device 1092.

25 Once plug 100 is positioned near distal
opening 1010, plug 100 can be inserted into aperture 1180
35 in wall 1150 of a patient's body cavity, as shown in
FIG. 11. Initially, end 1122 of delivery catheter 1090
is positioned within aperture 1180 (indicated by a dashed
40 30 line). Delivery catheter 1090 is then partially
reciprocated away from aperture 1180 along axis 1104 and
with respect to retention device 1092 (indicated by solid
line). This forces fingers 110 out of delivery
45 catheter 1090 and causes fingers 110 to spring out
35 radially away from central axis 1104, thereby causing
fingers 110 to engage side 1146 of wall 1150. At this
stage, fingers 110 conform to the wall and perimeter of
50 aperture 1180. Although FIG. 11 shows markers 114

5 attached to fingers 110 so they face wall 1050. it will
be appreciated that these markers could also be located
on the opposite side of these fingers.

After catheter 1090 is partially reciprocated
10 as shown in FIG. 11, catheter is further reciprocated as
shown in FIG. 12. End 1122 is withdrawn past locking
pins 1022 and retention device receptacles 1016. This
allows fingers 108 to spring out radially away from
15 central axis 1104 (from a position indicated by the
dashed lines) and engage patient's cavity wall 1150 at
surface 1148. As shown in FIG. 12, foldable plugging
structure 1006 at least partially unfolds to span
aperture 1180.

FIG. 13 shows plug 1300 partially installed in
15 aperture 1380 in wall 1350 of heart 1370. Plug 1300 of
FIG. 13 corresponds roughly to plug 100 of FIG. 11.
Delivery catheter 1390 and retention device 1392 are
25 guided to wall 1350 by delivery guide 1394. At this
stage of the installation, fingers 1310 are deployed and
engaged with surface 1346 of wall 1350. Fingers 1308
remain in delivery catheter 1390. Plugging
30 structure 1306 is positioned inside aperture 1380 and is
ready to conform to perimeter 1398 of aperture 1380 when
the remainder of plug 1300 is released from retention
device 1392.

FIG. 14 shows plug 1300 fully installed in
35 aperture 1380 in heart 1370 so that plugging
structure 1306 spans aperture 1380 and frame 1302
conforms to perimeter 1398. Fingers 1308 and 1310 are
engaged with opposite sides of wall 1450 to secure
40 plug 1300. Optional markers 1314 are provided on
ends 1312 of fingers 1310. In one embodiment according
to the invention, markers 1314 are radiopaque. FIG. 15
shows plug 1300 as installed in wall 1350 as viewed along
45 direction 15-15 of FIG. 14. Fingers 1308 are pressing
against surface 1348 of wall 1350. Plugging
structure 1306 spans the aperture in wall 1350 and is
50 substantially flush with perimeter 1398.

FIG. 16 shows another embodiment of a plug according to the invention. Plug 1600 includes frame 1602 which is structurally similar to frame 102 of FIG. 1. In this embodiment, however, plugging structure 1606 is supported by remote ends 1612 of fingers 1608. It will be appreciated that plugging structure could just as easily be mounted on fingers 1610. Optional marker rivets (not shown) can be placed in or near the apertures located at the of ends of fingers 1612. Optional marker rivets can also be used to attach plugging structure 1606 to frame 1602 and simultaneously provide a radiopaque marking device for locating and positioning plug 1600 using medical scanning instrumentation. Central axis 1604 passes through plugging structure 1606. Guide wire aperture 1640 allows a guide wire to be used to help control the position of plug 1600 during installation. FIG. 17 shows plug 1600 as viewed from the side opposite that shown in FIG. 16. As shown in FIG. 17, fingers 1610 and retention device receptacles 1616 can radially extend beyond plugging structure 1606.

FIG. 18 shows plug 1600 fully installed in aperture 1880 of wall 1850 in patient's heart 1870. Plugging structure 1606 is attached to remote ends 1612 of fingers 1608 and is drawn against surface 1848 by fingers 1612 as fingers 1608 press against side 1848. When installed, plugging structure 1606 has a greater diameter than cavity wall aperture 1880 and thus extends beyond perimeter 1898 of aperture 1880 in order to occlude aperture 1880. Fingers 1610 engage side 1846 of wall 1850 and hold plug 1600 in position.

FIG. 19 shows plug 1600 as viewed from line 19-19 of FIG. 18. Fingers 1610 of frame 1602 are not shown because from this perspective they are behind wall 1850. Perimeter 1898 of aperture 1880 is shown as a broken line because it is behind plugging structure 1606. Plugging structure 1606 can be supported by rivets 1614, which are located at ends 1612.

5 According to one embodiment, a plug has a
medial portion that defines a central passage with a
central axis. To allow the medial portion to expand
radially, any cross-section of that portion (and
10 preferably the entire frame) taken perpendicularly to the
central axis is substantially discontinuous. FIG. 20
shows frame 2002 in an "unfurled" state. Portions 2051
and 2052 of medial section 2050 would normally be
15 connected so that medial section 2050 forms a perforated
tube surrounding the plug's central axis. Plug 2000 can
include retention device receptacles 2016 on, for
example, remote ends of the fingers. Frame 2002 can also
include support structures 2030 for supporting a plugging
20 structure (not shown).

15 Medial section 2050, when in its operable
shape, forms a perforated tubular portion. FIG. 21 is a
perspective view of frame 2002 in its operable tubular
shape, including particularly medial section 2050 and
25 fingers 2008 and 2010 (remainder of fingers not shown for
the sake of simplicity). Perforated tubular portion 2050
defines longitudinal passage 2056 along central
axis 2004.
30

FIG. 22 shows a cross-sectional view of
perforated tubular portion 2050 taken along a plane that
25 is perpendicular to central axis 2004. The broken line
corresponding to portion 2050 indicates that the cross
section is discontinuous.
35

FIG. 23 shows a side view of tubular
portion 2050 and selected fingers 2008 and 2010 in two
40 different positions. As shown, fingers 2008 and 2010 are
attached to the axial ends of tubular portion 2550 and
are bent away from central axis 2004 into a splayed
position. These fingers can be heat treated before the
45 plug is installed to cause them to relax in this splayed
position. Fingers 2008 and 2010 can also be positioned
so that they point in a direction that is substantially
parallel to central axis 2004 (as shown by dashed lines,
50 which corresponds to the view of FIG. 22) for

5 installation of the plug. This position can be achieved,
for example, by inserting the plug into a delivery
device.

FIGS. 24 and 25 are similar to FIGS. 21 and 23,
5 respectively, but now include plugging structure 2006
mounted to frame 2002. Alternatively, a plugging
structure can be supported by support structures 2013 of
10 fingers 2008 and/or 2010. Alternatively, plug 2000 can
include two plugging structures, each of which can be
15 supported by support structures located at opposite axial
ends of plug 2000. For example, plug 2600, which
includes frame 2602, is shown in FIG. 26 in an unfurled
position for illustrative purposes. Frame 2602 includes
20 first plugging structure 2606, which is mounted on
support structures 2613 of fingers 2610 and second
15 plugging structure 2607, which is mounted on support
structures 2613 of fingers 2608. Support structures 2613
25 can also be used to mount markers or engage a retention
device.

20 In another embodiment according to this
invention, a frame having a perforated tubular portion
30 can be formed from a plastically deformable material and
can be installed using a balloon. FIG. 27, for example,
shows frame 2702 in an unfurled state similar to the
25 configuration of frame 2002 in FIGS. 20 and 26. In use,
35 end portion 2751 and 2752 are joined to form a tubular
structure surrounding central axis 2704. (Frame 2702 can
be formed from a tube, thereby eliminating the need to
join portions 2751 and 2752.)

40 When portions 2751 and 2752 are joined, medial
section 2750 becomes a perforated tubular portion
corresponding to perforated tubular portion 2050 shown in
FIG. 22. Although the perforated tubular portion shown
45 in FIG. 27 is axially longer than the perforated tubular
portion shown in FIGS. 21 and 22, it will be appreciated
35 that the length of the tubular portion can be matched to
the thickness of the wall being plugged.

5 As shown in FIG. 27, fingers 2708 and
fingers 2710 extend from opposite axial ends 2705
and 2706 of portion 2750, respectively. A plugging
structure (not shown) can be attached, for example, to
10 support structures 2730 to occlude the longitudinal
passage during use. Piercing points 2715 and barbs 2714
are for engaging opposite sides of a wall for securing
frame 2702 thereto.

15 FIG. 28 shows plug 2800, which includes
10 frame 2802 with delivery balloon 2888 inserted in
longitudinal passage 2856. Delivery balloon 2888 is
inflated enough to engage frame 2802 and allow delivery
of plug 2800 to a repair site inside a patient. Folded
20 or elastic plugging structure 2806 is deflected around
15 tip 2889 of balloon 2888. Plugging structure 2806 is
attached to frame 2802 at support structure 2830.
Plug 2800 can have barbs 2815, for example, for engaging
25 a patient's body tissue.

FIG. 29 shows a cross-sectional view of
20 plug 2800 being positioned in aperture 2980 in cavity
wall 2950. During installation of plug 2800,
30 balloon 2888 engages the inside of frame 2802. Plugging
structure 2806 is deflected around balloon tip 2889.
Next, plug 2800 is inserted with balloon 2888 into
25 aperture 2980. Balloon 2888 is then inflated, causing
35 frame 2802 to expand radially and to contract along its
central axis 2804, thereby forcing barbs 2815 to pierce
opposite sides 2946 and 2948 of wall 2950. This also
causes perforated tubular portion 2852 to conform to
40 perimeter 2898. If plugging structure 2806 is secured to
30 perforated tubular portion 2852, it too is stretched or
unfolded across aperture 2980.

FIG. 30 shows plug 2800 installed in
45 aperture 2980 after frame 2802 is deformed by the
35 expansion of balloon 2888. At this stage, balloon 2888
has been removed from perforated tubular portion 2852.
The perforations (i.e., the holes) in portion 2852 allow

the axial length of perforated tubular portion 2852 to decrease as its radius increases.

FIG. 31 shows plug 2800 being delivered to aperture 2980 in heart 2970. Plug 2800 is supported by partially inflated balloon 2888 and guided through a patient's body tissue and/or tubing via delivery guide 2894 until it is positioned with barbs 2815 on opposite sides of wall 2950.

After delivery of plug 2800 to aperture 2980, plug 2800 can be fully installed by further expanding balloon 2888, thereby causing frame 2802 to deform and secure itself as shown in FIG. 32. After plug 2800 is secured, balloon 2888 is deflated and removed. When installed, tubular portion 2852 conforms to perimeter 2998 and plugging structure 2806 spans and occludes blood flow through the aperture.

In another embodiment of the invention, a plug is provided for occluding a lumen of a patient's body tubing. FIG. 33 shows occlusion plug 3300, which includes frame 3302. Plug 3300 is similar to aperture plug 2700 (shown in FIG. 27), but has barbs (or points) that extend from fingers 3308 on only one axial end 3305 of medial section 3350. It will be appreciated that points 3315 are not always necessary, but may be included in plugs where positive anchoring is desired. Frame 3302 is shown in FIG. 33 in an "unfurled" state, but as in the embodiments discussed above, would be joined to form a perforated tubular portion. Support structures 3330 can also be provided for securing a plugging structure (not shown).

FIG. 34 shows occlusion plug 3400 mounted on partially inflated balloon 3488. Balloon 3488 occupies longitudinal passage 3456 along central axis 3456. Plugging structure 3406 is attached to frame 3402 at support structures 3430 in medial section 3452 and is deflected around tip 3489 of balloon 3488. Piercing points 3415, which can be barbed, extend away from

5 central axis 3456 and are destined to be embedded in the interior wall of a patient's body tubing.

Occlusion plug 3500, which is shown in FIG. 35,

is constructed according to this invention, but includes

10 5 a frame with a different profile from that shown in

FIG. 33. FIG. 35 shows a partial view of plug 3500 in

the unfurled state. Like each of the other embodiments

discussed above, medial portion 3550 can radially expand

15 and axially contract when a balloon is inflated therein.

20 In particular, each of the rectangular units that make up

frame 3502 can stretch, such that length l and width w

vary inversely.

FIG. 36 shows the deployment of occlusion

20 plug 3600 in a patient's blood vessel 3640 having

15 aneurysm 3650. Arrow A shows the normal direction of

blood flow through blood vessel 3640. Because of

25 aneurysm 3650, it may be desirable to occlude blood

vessel 3640 upstream from aneurysm 3650. As already

explained above, with reference to plug 2800, for

20 example, plug 3600 is mounted on balloon 3688 and

positioned upstream of aneurysm 3650. As balloon 3688 is

30 inflated, perforated tubular portion 3652 expands

radially causing perforated tubular portion 3652 to

conform to inner wall 3642 of blood vessel 3640.

25 Plugging structure 3606 is attached to frame 3602 at

35 points along the circumference of tubular portion 3652

and is thus stretched to occlude lumen 3644 of blood

vessel 3640. As perforated tubular portion 3652 expands

radially, it contracts axially and causes piercing

40 points 3615 to engage walls 3642 and thus anchor

plug 3600.

It will be understood that the foregoing is

only illustrative of the principles of the invention, and

45 that various modifications can be made by those skilled

35 in the art without departing from the scope and spirit of

the invention.

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Claims

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The Invention Claimed Is

1. A plug for closing an aperture in a wall of a patient's body cavity, said plug comprising:

a frame having a central axis comprising:

a first plurality of fingers configured to engage an interior surface of said wall of said body cavity;

a second plurality of fingers attached to said first plurality, wherein said second plurality is configured to engage an exterior surface of said wall of said body cavity, and wherein said pluralities of fingers are positioned substantially circumferentially with respect to said axis; and

a plugging structure that spans said aperture when said plug is inserted in said aperture, wherein said plugging structure is attached to said frame, and wherein any cross-section of said frame that lies in a plane substantially perpendicular to said axis is discontinuous.

2. The plug of claim 1 wherein said plug can be detected using fluoroscopy.

3. The plug of claim 1 wherein said first and second pluralities of fingers are formed from a unitary body.

4. The plug of claim 1 wherein said frame comprises an elastic material.

5. The plug of claim 4 wherein said frame comprises nitinol.

6. The plug of claim 1 wherein at least one finger of at least one of said pluralities of fingers extends substantially radially away from said central axis.

5 7. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a marker structure.

10 8. The plug of claim 7 wherein said marker
structure is radiopaque.

15 9. The plug of claim 7 wherein said marker
structure is a marker band.

20 10. The plug of claim 9 wherein said finger
has an end portion and said marker band is crimped to
said end portion.

 11. The plug of claim 7 wherein said marker
structure is a rivet.

25 12. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a retention device receptacle.

30 13. The plug of claim 12 wherein said
retention device receptacle is a locking pin aperture.

35 14. The plug of claim 12 wherein said
retention device receptacle is a nose cone cover.

40 15. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a pointed end portion located remotely from said central
axis.

45 16. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a barbed end portion located remotely from said central
axis.

5 17. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers is
curved, said curve being concave toward a plane
perpendicular to said central axis and passing
10 5 substantially between said first and second pluralities
of fingers.

15 18. The plug of claim 1 wherein said fingers
have end portions that are proximal to said central axis
and said end portions define a substantially round cross
section.

20 19. The plug of claim 1 wherein said fingers
have end portions that are proximal to said central axis
and said end portions define a substantially elliptical
cross section.

25 20. The plug of claim 1 wherein substantially
all of said fingers of at least one of said pluralities
of fingers are of substantially the same length.

30 21. The plug of claim 1 wherein different
fingers of at least one of said pluralities of fingers
have different lengths.

35 22. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a different flexural stiffness at different points along
its length.

40 23. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a different thickness at different points along its
45 length.

50 24. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a different width at different points along its length.

5 25. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
a free end portion comprising an end structure configured
to facilitate releasable retention of said finger by a
10 5 plug delivery device.

 26. The plug of claim 1 further comprising an
elastic web between adjacent ones of said fingers.

15 27. The plug of claim 26 wherein said web
comprises silicone.

20 28. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
an end portion proximal to said central axis for
supporting said plugging structure.

25 29. The plug of claim 28 wherein said end
portions have support structures with which to affix said
plugging structure.

30 30. The plug of claim 1 wherein at least one
finger of at least one of said pluralities of fingers has
an end portion remote from said central axis for
supporting said plugging structure.

35 31. The plug of claim 30 wherein said end
portion has a support structure with which to affix said
plugging structure.

40 32. The plug of claim 1 wherein said plugging
structure is elastic.

45 33. The plug of claim 1 wherein said plugging
structure can be unfolded.

50 34. The plug of claim 1 wherein said plugging
structure comprises polymeric material.

5 35. The plug of claim 1 wherein said plugging
structure comprises DACRON®.

10 36. The plug of claim 1 wherein said plugging
structure comprises cloth.

 37. The plug of claim 1 wherein said plugging
structure is sewn to said frame.

15 38. The plug of claim 1 wherein said plugging
structure has a guide wire aperture through which a guide
wire can pass.

20 39. The plug of claim 38 wherein said guide
wire aperture can substantially self close when said
guide wire is removed from said guide wire aperture.

25 40. The plug of claim 1 wherein said frame is
insertable into a delivery tube by positioning said
fingers in a direction substantially parallel to said
central axis.

30 41. The plug of claim 1 wherein said second
plurality of fingers is integral with said first
plurality of fingers.

35 42. The plug of claim 1 wherein said aperture
has a perimeter and said frame can conform to said
perimeter.

40 43. A plug comprising:
 a perforated tubular portion having a
longitudinal passage, wherein any cross-section of said
45 perforated tubular portion in a plane perpendicular to
5 said passage is discontinuous;
 a plurality of fingers attached to said
tubular portion and extending from an axial end of said
50 perforated tubular portion, wherein any cross-section of

5 said plurality of fingers in a plane perpendicular to
10 said passage is discontinuous; and
 a plugging structure substantially
 occluding said passage.

10 44. The plug of claim 43 wherein said plug can
 be detected using fluoroscopy.

15 45. The plug of claim 43 wherein said
 perforated tubular portion and said plurality of fingers
 are formed from a unitary body.

20 46. The plug of claim 43 further comprising a
 second plurality of fingers attached to said tubular
 portion and extending from a second axial end of said
 perforated tubular portion.

25 47. The plug of claim 46 wherein said plug can
 be detected using fluoroscopy.

30 48. The plug of claim 46 wherein said
 perforated tubular portion and said first and second
 pluralities of fingers are formed from a unitary body.

35 49. The plug of claim 46 wherein said
 perforated tubular structure and said fingers comprise an
 elastic material.

40 50. The plug of claim 49 wherein said
 perforated tubular structure and said fingers frame
 comprise nitinol.

45 51. The plug of claim 46 wherein at least one
 finger of said pluralities of fingers can be positioned
 to extend substantially radially away from said
 longitudinal passage.

5

52. The plug of claim 46 wherein at least one finger of said plurality of fingers has a marker structure.

10

53. The plug of claim 52 wherein said marker structure is radiopaque.

15

54. The plug of claim 52 wherein said marker structure is a marker bands.

20

55. The plug of claim 54 wherein said finger has an end portion and said marker band is crimped to said end portion.

25

56. The plug of claim 52 wherein said marker structure is a rivet.

30

57. The plug of claim 46 wherein at least one finger of at least one of said pluralities of fingers has a retention device receptacle.

58. The plug of claim 57 wherein said retention device receptacle is a locking pin aperture.

35

59. The plug of claim 58 wherein said retention device receptacle is a nose cone cover.

40

60. The plug of claim 46 wherein at least one finger of at least one of said pluralities of fingers has a pointed end portion located remotely from said central axis.

45

61. The plug of claim 46 wherein at least one finger of at least one of said pluralities of fingers has a barbed end portion located remotely from said central axis.

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5 62. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers is
curved, said curve being concave toward a plane
perpendicular to said central axis and passing
10 5 substantially between said first and second pluralities
of fingers.

15 63. The plug of claim 46 wherein said
perforated tubular portion defines a substantially round
cross section as viewed in a direction of said
longitudinal axis.

20 64. The plug of claim 46 wherein said
perforated tubular portion defines a substantially
elliptical cross section as viewed in a direction of said
longitudinal passage.

25 65. The plug of claim 46 wherein substantially
all of said fingers of at least one of said pluralities
are of substantially similar length.

30 66. The plug of claim 46 wherein different
ones of the fingers of at least one of said pluralities
are of different lengths.

35 67. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
different flexural stiffness along its length.

40 68. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
different thickness along its length.

45 69. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
different width along its length.

5 70. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
a free end portion comprising an end structure configured
to facilitate releasable retention of said finger by a
5 plug delivery device.

10 71. The plug of claim 46 further comprising an
elastic web between adjacent ones of said fingers.

15 72. The plug of claim 71 wherein the web
comprises silicone.

20 73. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
an end portion proximal to said central axis for
supporting said plugging structure.

25 74. The plug of claim 46 wherein at least one
finger of at least one of said pluralities of fingers has
an end portion remote from said central axis for
supporting said plugging structure.

30 75. The plug of claim 74 wherein said end
portion has a support structure with which to affix said
plugging structure.

35 76. The plug of claim 46 wherein said
perforated tubular portion has at least one support
structure with which to affix said plugging structure.

40 77. The plug of claim 46 wherein said plugging
structure is elastic.

45 78. The plug of claim 46 wherein said plugging
structure can be unfolded.

50 79. The plug of claim 46 wherein said plugging
structure comprises polymeric material.

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80. The plug of claim 46 wherein said plugging structure comprises DACRON®.

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81. The plug of claim 46 wherein said plugging structure comprises cloth.

15

82. The plug of claim 46 wherein said plugging structure is sewn to said frame.

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83. The plug of claim 46 wherein said plugging structure has a guide wire aperture through which a guide wire can pass.

25

84. The plug of claim 83 wherein said guide wire aperture can substantially self close after said guide wire is removed.

30

85. The plug of claim 46 wherein said frame may be inserted into a delivery tube by extending said fingers in a direction substantially parallel to said longitudinal passage.

35

86. The plug of claim 46 wherein said perforated tubular portion can conform to a perimeter of a hole in a wall of a patient's body cavity.

40

87. The plug of claim 46 wherein said perforated tubular portion can contract longitudinally as it expands radially.

45

88. The plug of claim 46 wherein said perforated tubular portion is plastically deformable.

50

89. The plug of claim 88 wherein said perforated tubular portion comprises stainless steel.

90. The plug of claim 89 wherein said tubular portion comprises tantalum.

55

5 91. The plug of claim 88 wherein said
perforated tubular portion can be conformed to a
perimeter of a hole in a wall of a patient's body cavity
using a balloon to expand said perforated tubular
10 5 portion.

 92. The plug of claim 88 wherein said
perforated tubular portion can contract longitudinally as
15 it expands radially.

 93. The plug of claim 43 wherein said
perforated tubular portion and said fingers comprise an
20 elastic material.

 94. The plug of claim 93 wherein said
perforated tubular portion and said fingers comprise
25 nitinol.

 95. The plug of claim 43 wherein at least one
of said fingers extends substantially radially away from
30 said central axis.

 96. The plug of claim 43 wherein at least one
of said fingers has a marker structure.

35 97. The plug of claim 96 wherein said marker
structure is radiopaque.

40 98. The plug of claim 96 wherein said marker
structure is a marker band.

45 99. The plug of claim 98 wherein said finger
has an end portion and said marker band is crimped to
said end portion.

50 100. The plug of claim 96 wherein said marker
structure is a rivet.

5 101. The plug of claim 43 wherein at least one
of said fingers has a pointed end portion located
remotely from said central axis.

10 102. The plug of claim 43 wherein at least one
of said fingers has a barbed end portion located remotely
from said central axis.

15 103. The plug of claim 43 wherein at least one
of said fingers is curved, said curve being concave
toward a plane perpendicular to said central axis and
passing through said perforated tubular portion.

20 104. The plug of claim 43 wherein said
perforated tubular portion defines a substantially round
cross section as viewed in a direction of said
longitudinal passage.

25 105. The plug of claim 43 wherein said
perforated tubular portion defines a substantially
elliptical cross section as viewed in a direction of said
30 longitudinal passage.

35 106. The plug of claim 43 wherein substantially
all of said fingers are of substantially similar length.

40 107. The plug of claim 43 wherein different
ones of the fingers are of different lengths.

45 108. The plug of claim 43 wherein at least one
of said fingers has different flexural stiffness along
its length.

50 109. The plug of claim 43 wherein at least one
of said fingers has different thickness along its length.

55 110. The plug of claim 43 wherein at least one
of said fingers has different width along its length.

5 111. The plug of claim 43 wherein at least one
of said fingers has a free end portion comprising an end
structure configured to facilitate releasable retention
of said finger by a plug delivery device.

10 112. The plug of claim 43 further comprising an
elastic web between adjacent ones of said fingers.

15 113. The plug of claim 112 wherein the web
comprises silicone.

20 114. The plug of claim 43 wherein at least one
of said fingers has an end portion proximal to said
central axis for supporting said plugging structure.

25 115. The plug of claim 114 wherein said end
portion has a support structure with which to affix said
plugging structure.

30 116. The plug of claim 43 wherein said
perforated tubular portion has at least one support
structure for supporting said plugging structure.

35 117. The plug of claim 43 wherein said plugging
structure is elastic.

40 118. The plug of claim 43 wherein said plugging
structure can be unfolded.

45 119. The plug of claim 43 wherein said plugging
structure comprises polymeric material.

50 120. The plug of claim 43 wherein said plugging
structure comprises DACRON®.

55 121. The plug of claim 43 wherein said plugging
structure comprises cloth.

5 122. The plug of claim 43 wherein said plugging
structure is sewn to said frame.

10 123. The plug of claim 43 wherein said plugging
structure has a guide wire aperture through which a guide
wire can pass.

15 124. The plug of claim 123 wherein said guide
wire aperture can substantially self close after said
guide wire is removed.

20 125. The plug of claim 43 wherein said frame
may be inserted into a delivery tube by extending said
fingers in a direction substantially parallel to said
longitudinal passage.

25 126. The plug of claim 43 wherein said
perforated tubular portion can conform to a perimeter of
a defect in a wall of a patient's body cavity.

30 127. The plug of claim 43 wherein said
perforated tubular portion can contract longitudinally as
it expands radially.

35 128. The plug of claim 43 wherein said
perforated tubular portion is plastically deformable.

40 129. The plug of claim 128 wherein said
perforated tubular portion comprises stainless steel.

 130. The plug of claim 128 wherein said
perforated tubular portion comprises tantalum.

45 131. The plug of claim 128 wherein said
perforated tubular portion can be conformed to a
perimeter of a hole in a wall of a patient's body cavity
using a balloon to expand said perforated tubular
50 5 portion.

5

132. The plug of claim 128 wherein said perforated tubular portion can contract longitudinally as it expands radially.

10

133. A method for plugging an aperture in a wall of a patient's body cavity comprising:

15

positioning in said aperture a conformable plug having a first plurality of fingers, a second plurality of fingers, and a central axis, wherein said pluralities are arranged about said axis at opposite axial ends, and wherein said plug also has a plugging structure;

20

conforming said plug to said aperture; and
10 securing said plug in said aperture.

25

134. The method of claim 133 wherein said positioning comprises locating said plug using fluoroscopy.

30

135. The method of claim 133 wherein said positioning comprises providing a delivery structure for installing said plug.

35

136. The method of claim 135 wherein said positioning further comprises:

extending said fingers in a direction substantially parallel to said central axis; and
5 inserting said plug into a sleeve.

40

137. The method of claim 136 wherein said positioning further comprises engaging at least one of said fingers with a locking pin.

45

138. The method of claim 137 wherein said positioning further comprises releasing at least one finger from a locking pin.

50

55

5 139. The method of claim 135 wherein said positioning further comprises inserting said delivery structure through an insertion aperture in a patient's body tissue.

10 140. The method of claim 135 wherein said positioning further comprises shifting said delivery structure relative to said plug and said aperture so that
15 5 (1) said delivery structure is removed from said aperture but said plug extends through said aperture; (2) said fingers extend out from said axis, wherein each of said first and second pluralities on opposite sides of said wall; and (3) said plugging structure substantially
20 occludes said aperture.

 141. The method of claim 140 wherein said positioning further comprises allowing said fingers to
25 engage said respective opposite sides of said wall.

 142. The method of claim 140 wherein said conforming comprises allowing said plug to elastically
30 expand in said aperture until said plug substantially conforms to a perimeter of said aperture.

 143. The method of claim 140 wherein said positioning further comprises allowing said plug to
35 elastically contract longitudinally to cause said fingers to engage said respective opposite sides of said wall.

40 144. The method of claim 143 wherein said allowing further comprises allowing said plug to substantially center itself with respect to said wall in a direction along said longitudinal passage.

45 145. A method for occluding blood flow in a tube of a patient's circulatory system, said method comprising:
50

5 positioning in said tube a conformable
5 plug having a first plurality of fingers, a tubular
portion, a plugging structure, and a central axis,
10 wherein said plurality of fingers is arranged
circumferentially about said central axis and wherein
said plugging structure spans across said tubular
10 portion;

conforming said plug to said tube; and
15 securing said plug in said tube.

146 The method of claim 145 wherein said
positioning comprises locating said plug using
20 fluoroscopy.

147. The method of claim 145 wherein said
positioning comprises providing a delivery balloon for
25 installing said plug.

148. The method of claim 145 wherein said
positioning further comprises:
30 inserting said delivery balloon in said
tubular portion; and

5 delivering said plug through the patient's
body tissue to said tube.

149. The method of claim 148 wherein said
delivering further comprises inserting said balloon and
said plug through an insertion aperture in a patient's
35 body tissue.

150. The method of claim 148 wherein said
positioning further comprises moving said plug mounted on
said balloon through a patient's existing body tubing so
45 that said plug is positioned in said tube at a desired
5 location.

151. The method of claim 150 wherein said
50 conforming comprises:

5

expanding said balloon; and

radially enlarging said tubular portion

5 until said tubular portion until said plurality of
fingers engages with an inside surface of said tube.

10

wherein said plugging structure substantially occludes
said tube.

15

152. The method of claim 151 wherein said
enlarging comprises plastically deforming said plug.

20

153. The method of claim 151 wherein said
positioning further comprises allowing said plug to
substantially center itself with respect to said wall in
a direction along said longitudinal passage.

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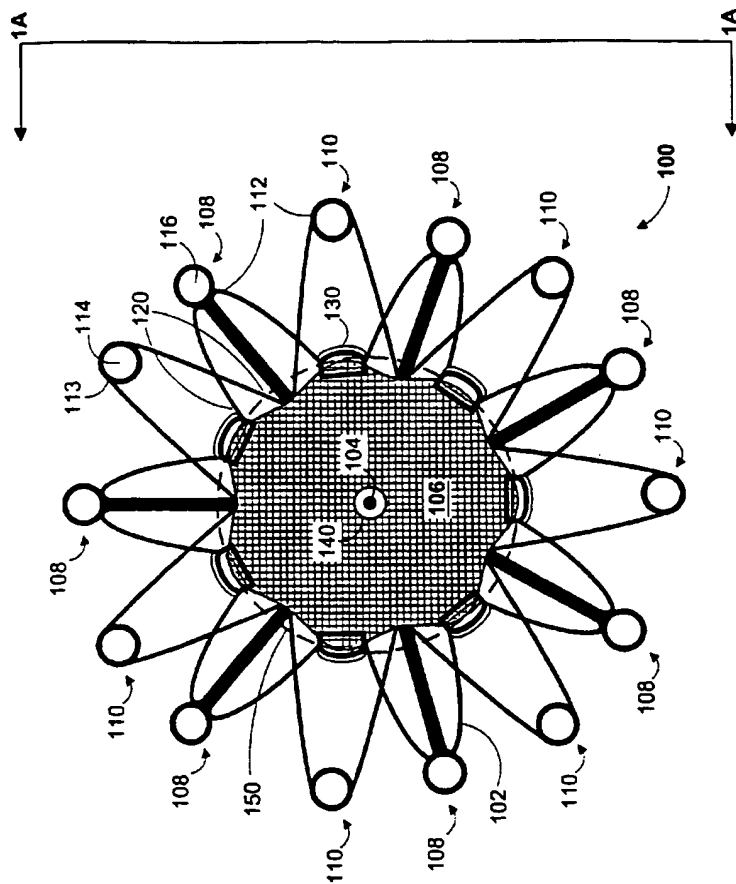


FIG. 1

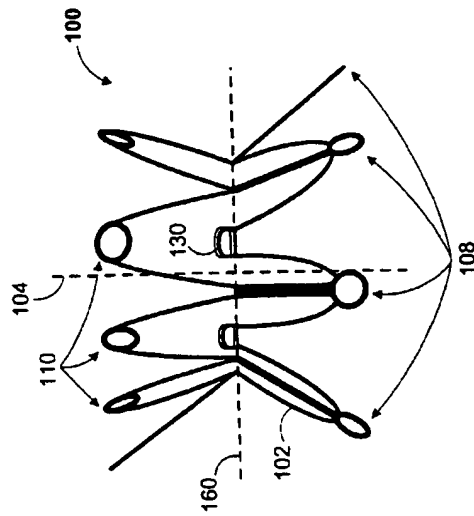
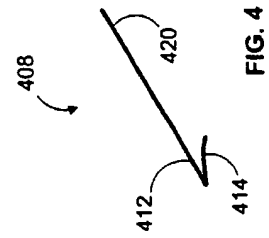
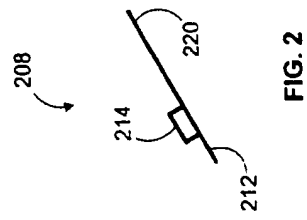
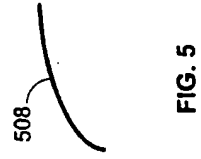
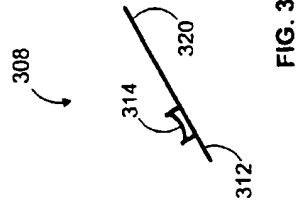


FIG. 1A



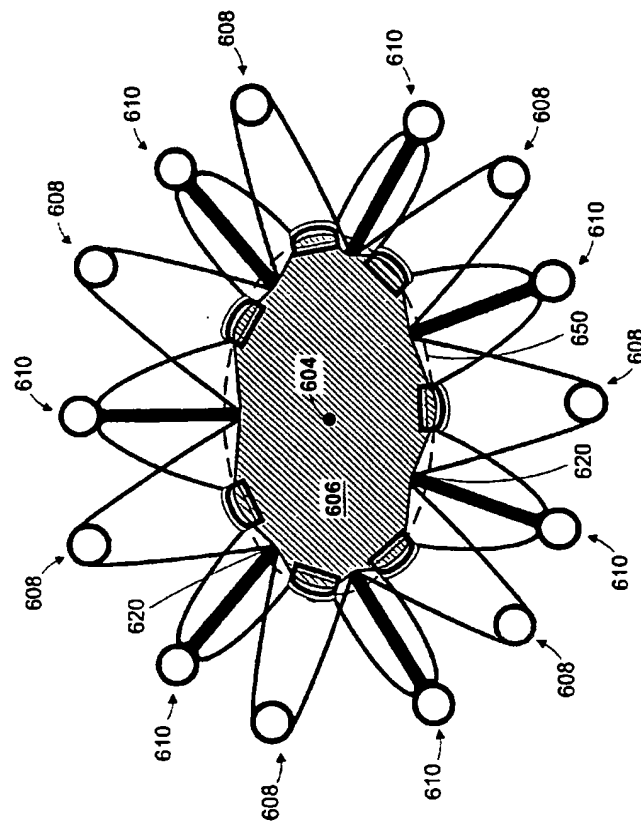


FIG. 6

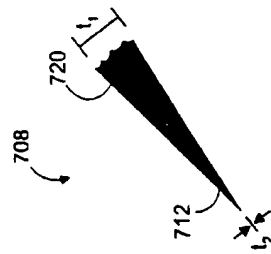


FIG. 7

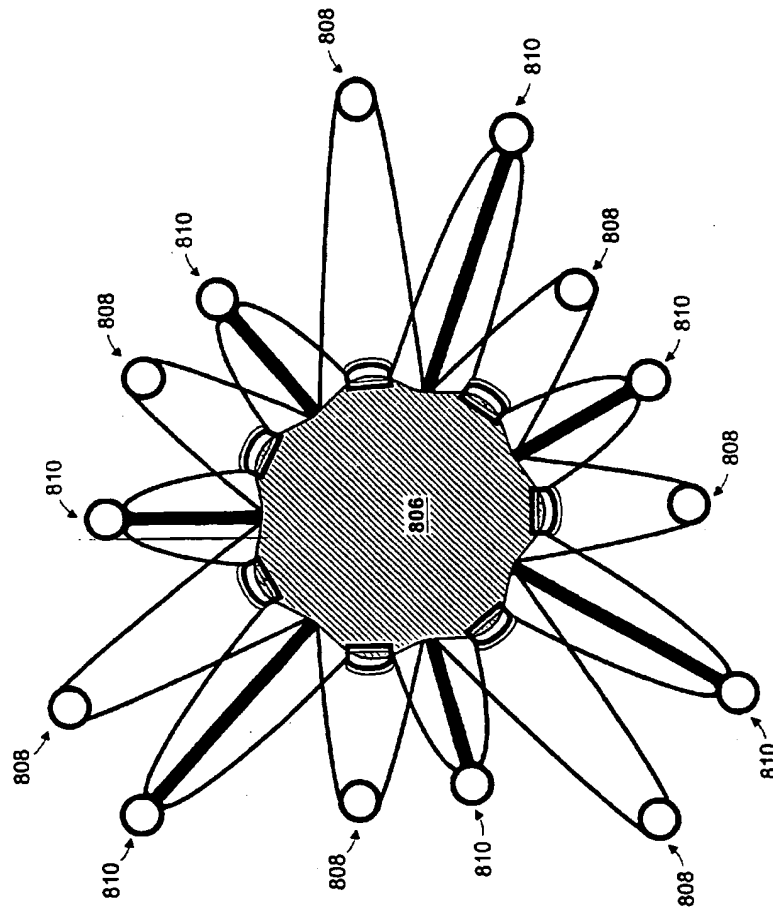


FIG. 8

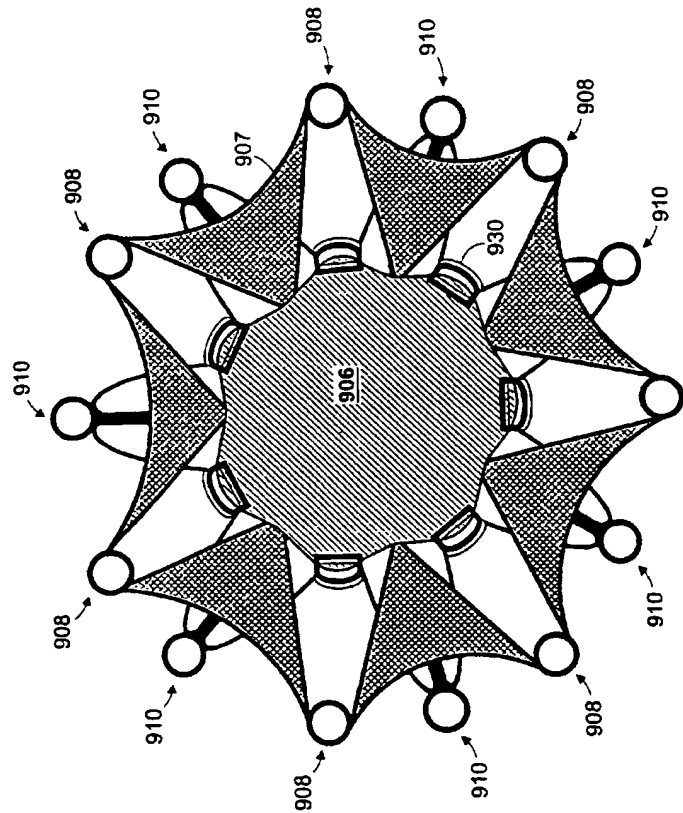


FIG. 9

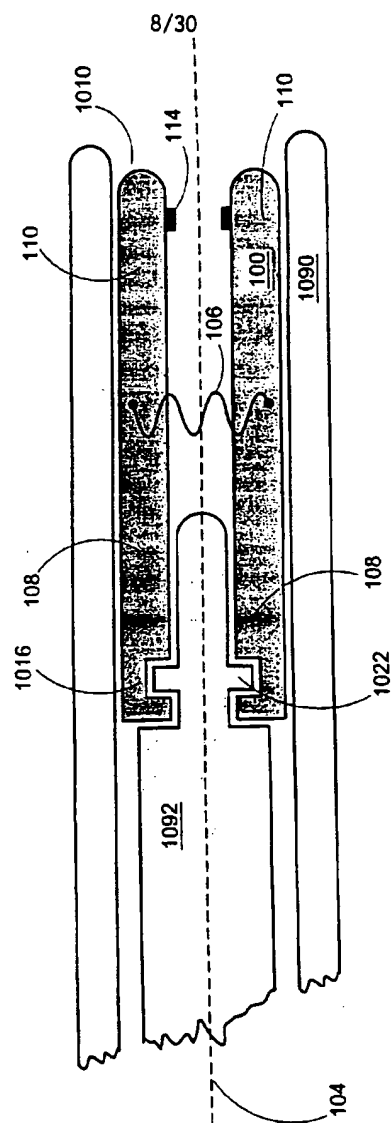


FIG. 10

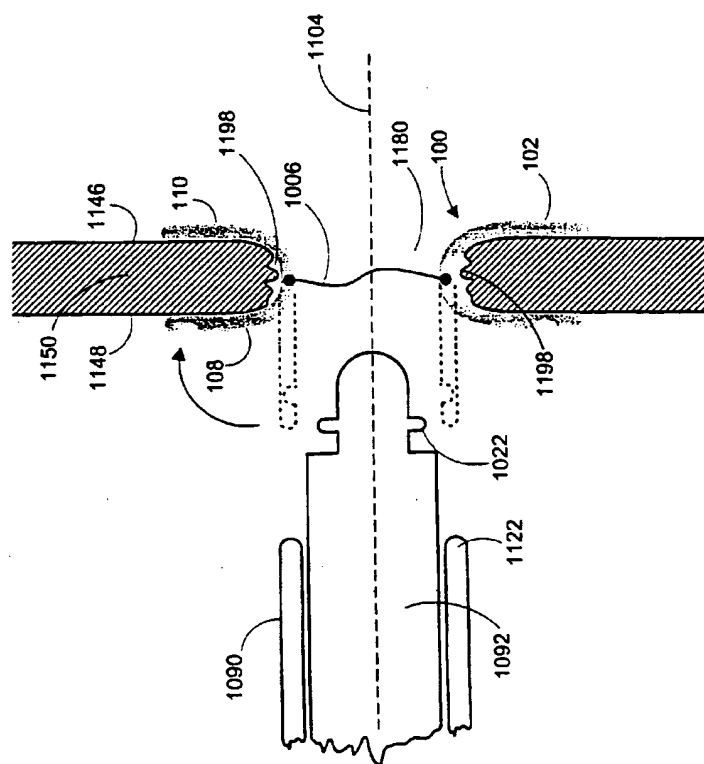


FIG. 12

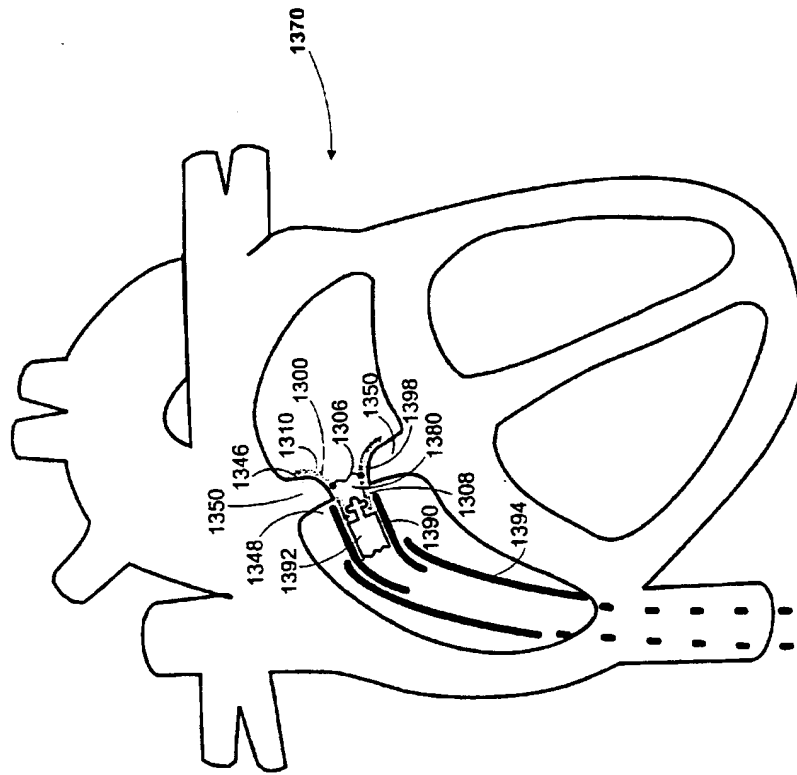


FIG. 13

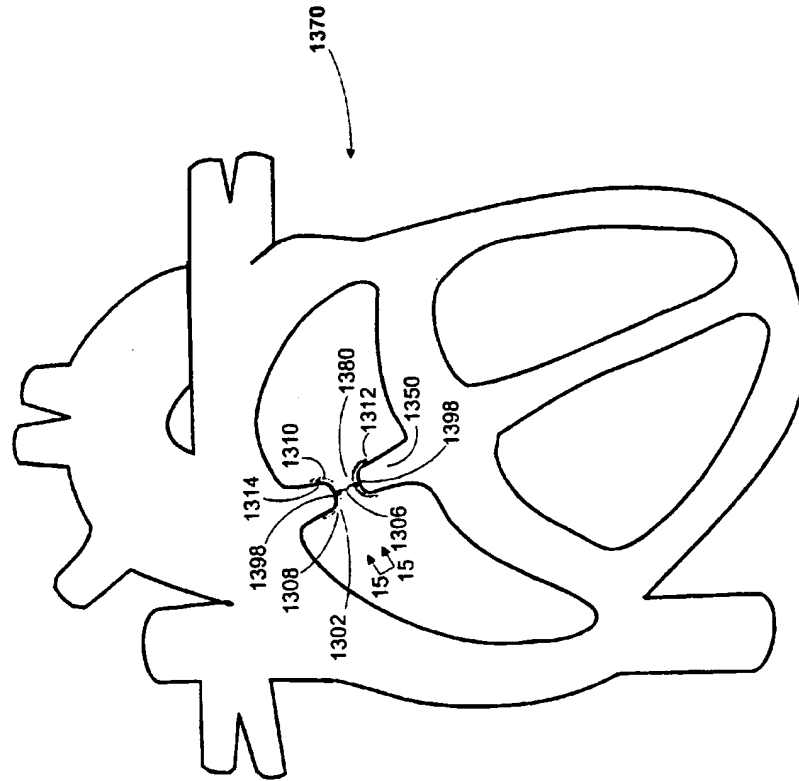


FIG. 14

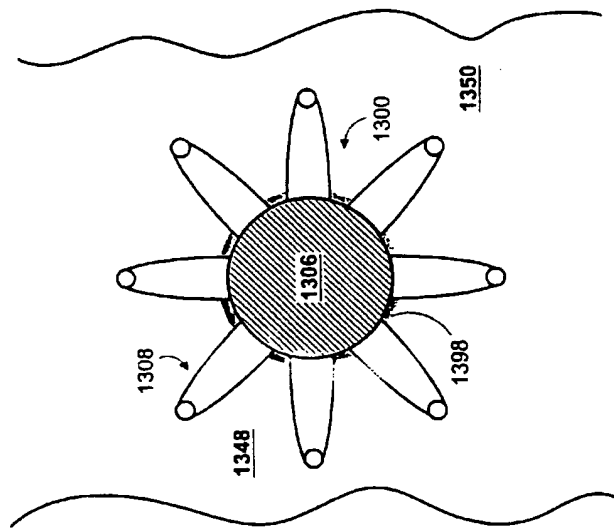


FIG. 15

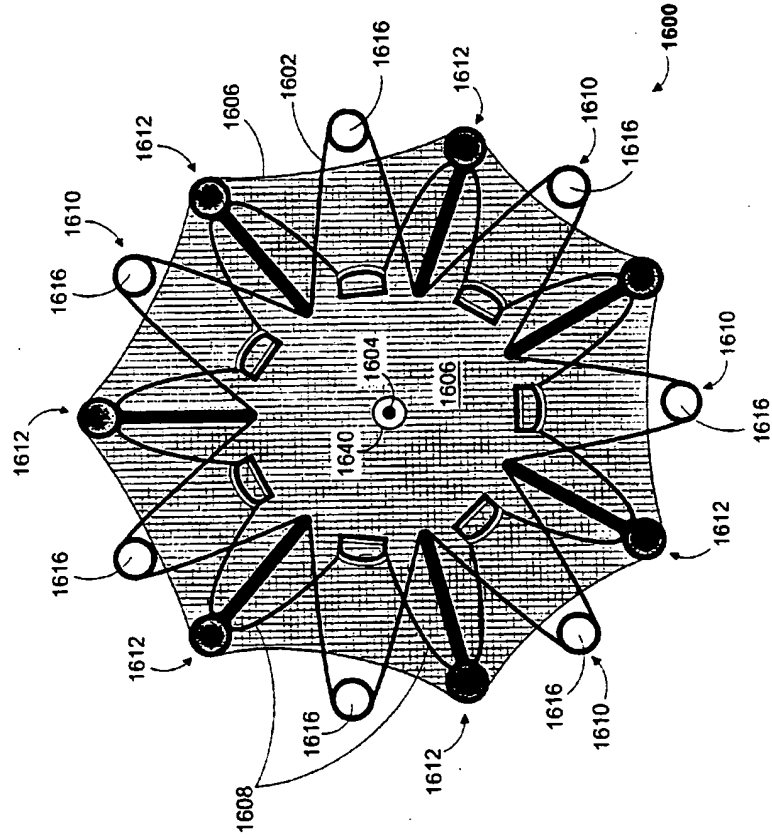


FIG. 16

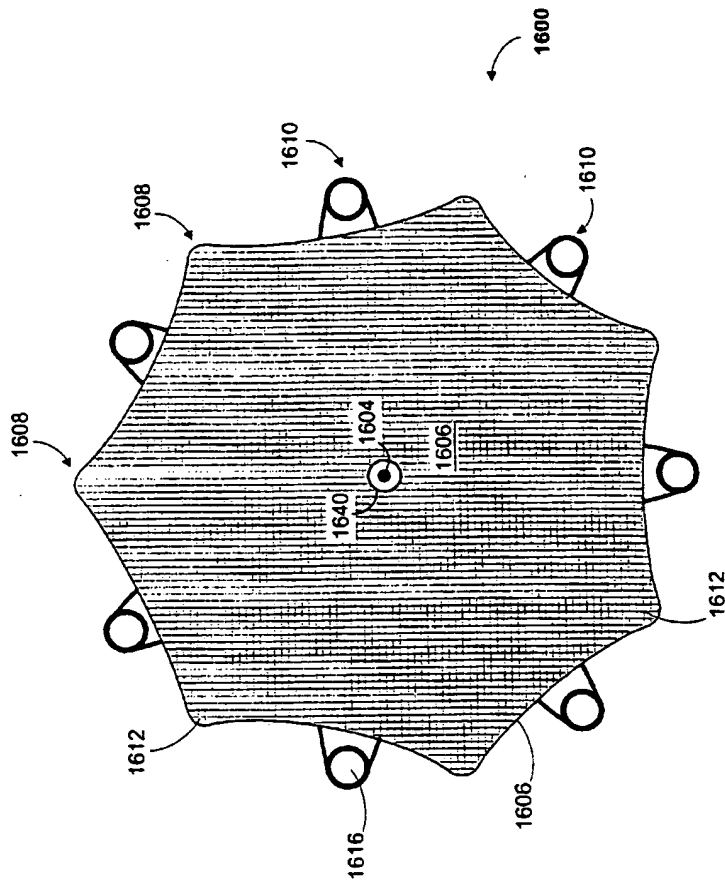


FIG. 17

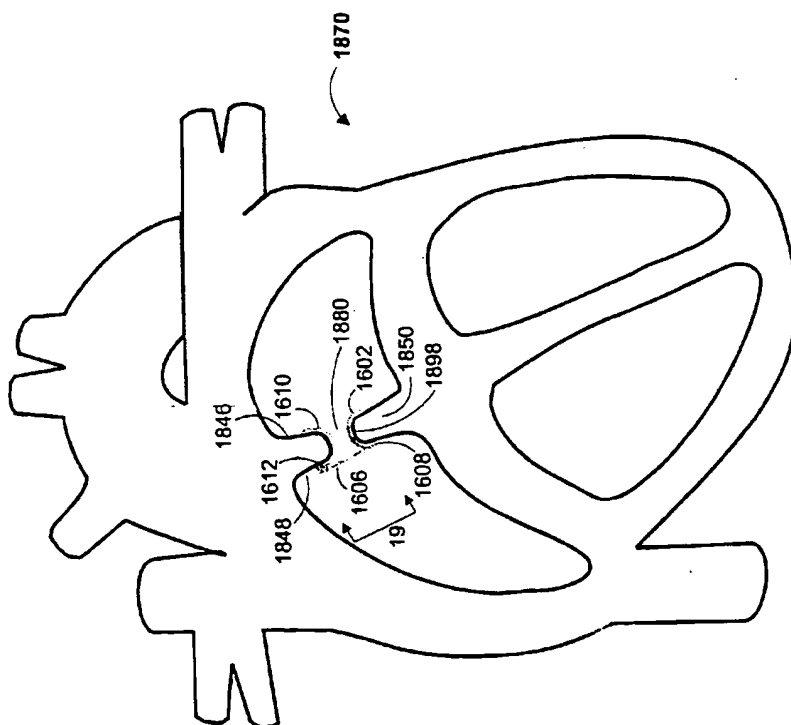


FIG. 18

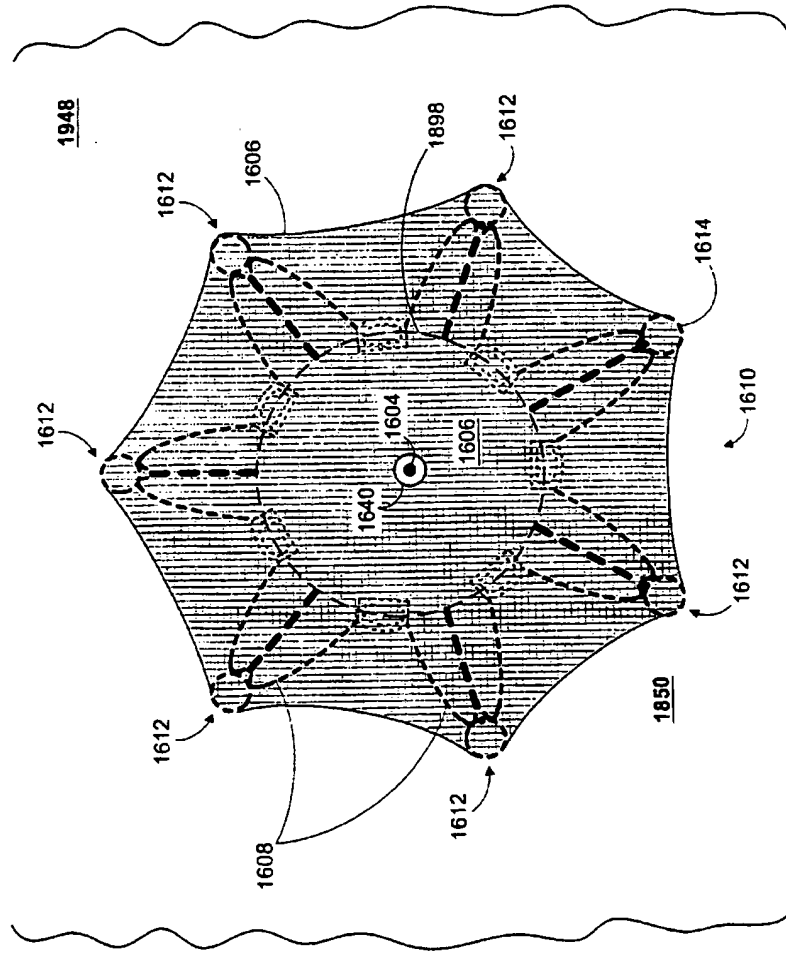


FIG. 19

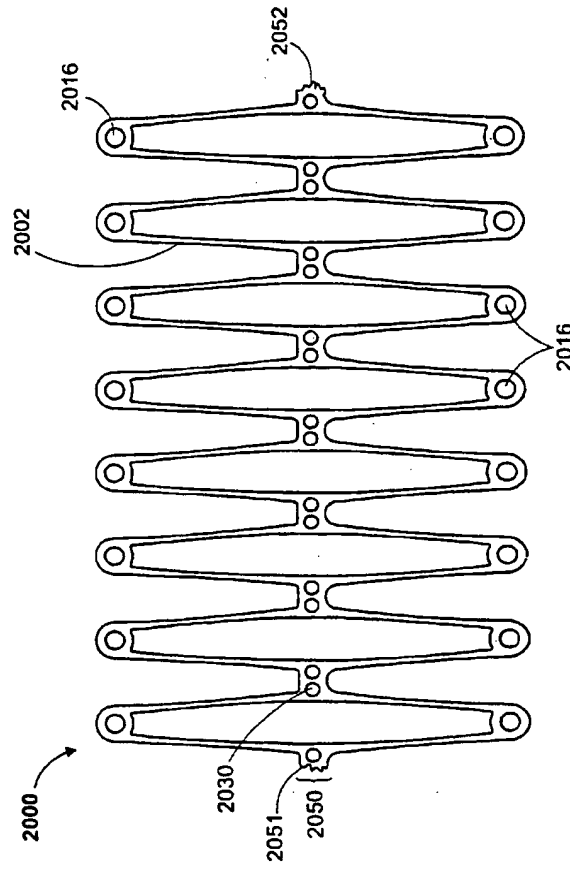
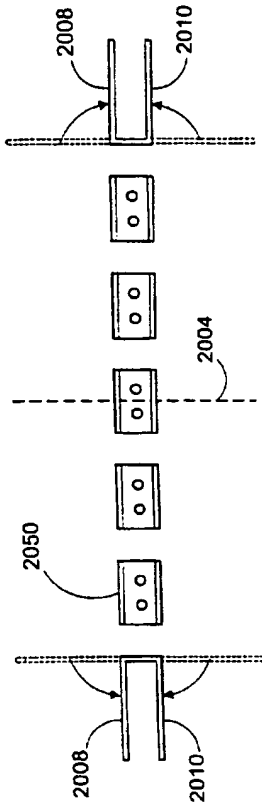
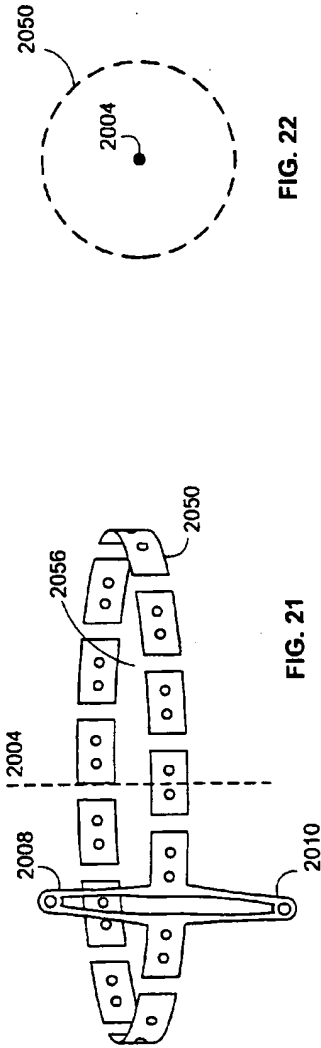


FIG. 20



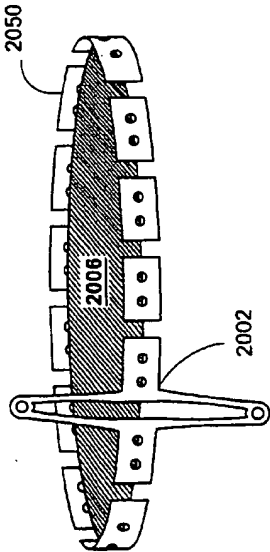


FIG. 24

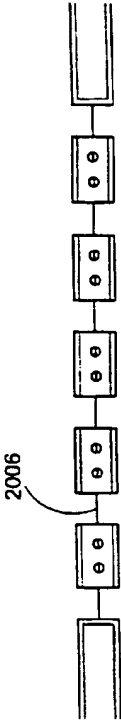


FIG. 25

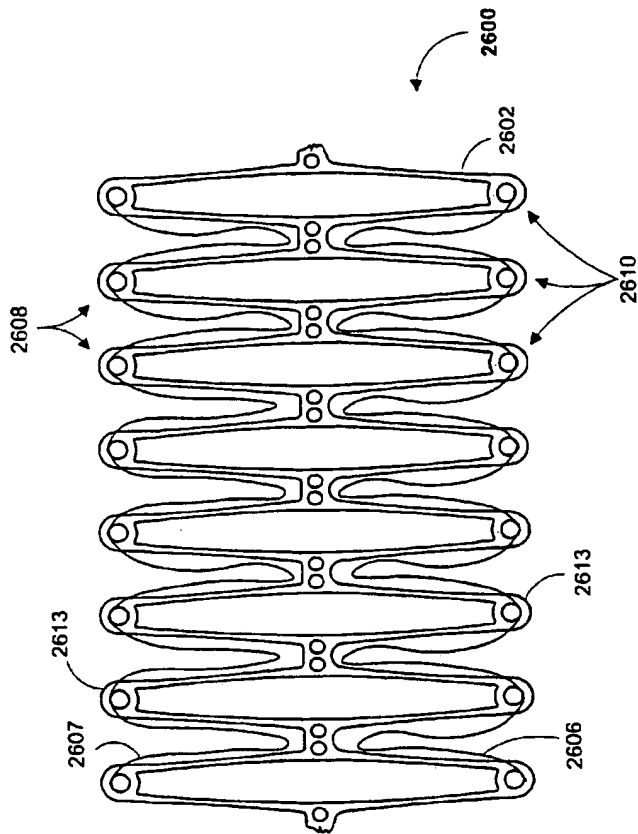
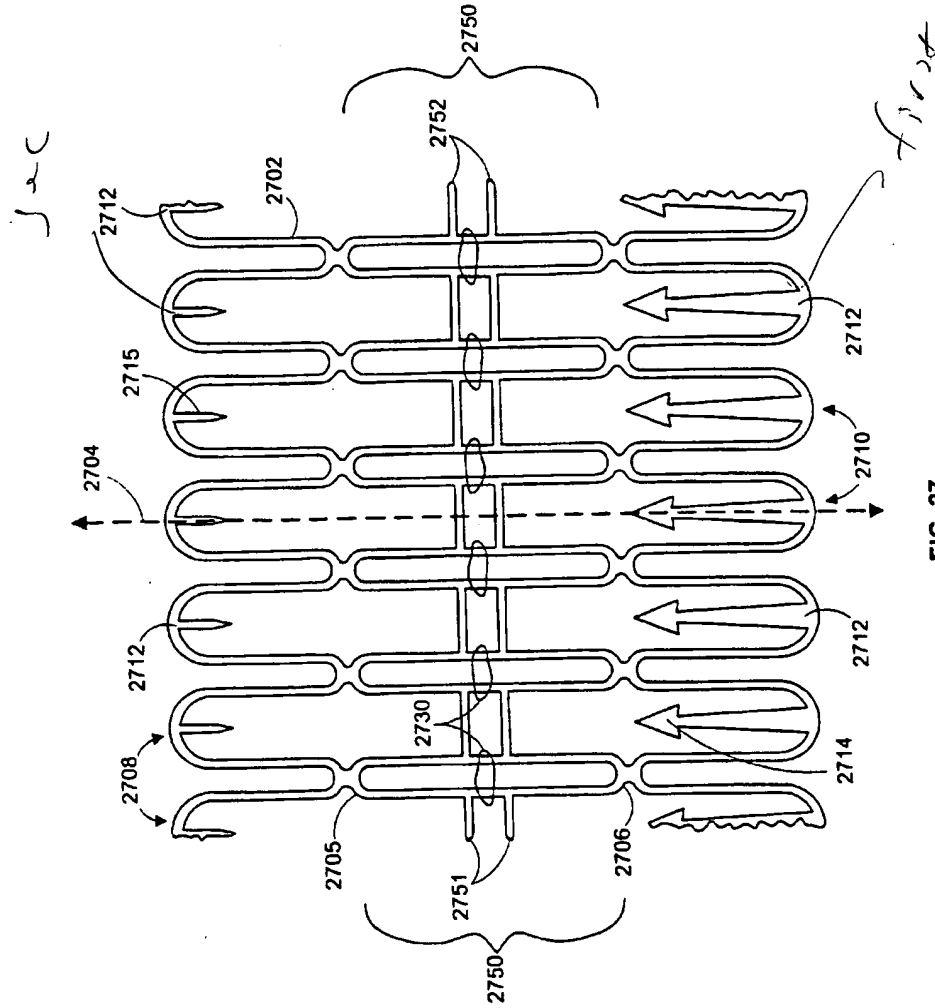


FIG. 26



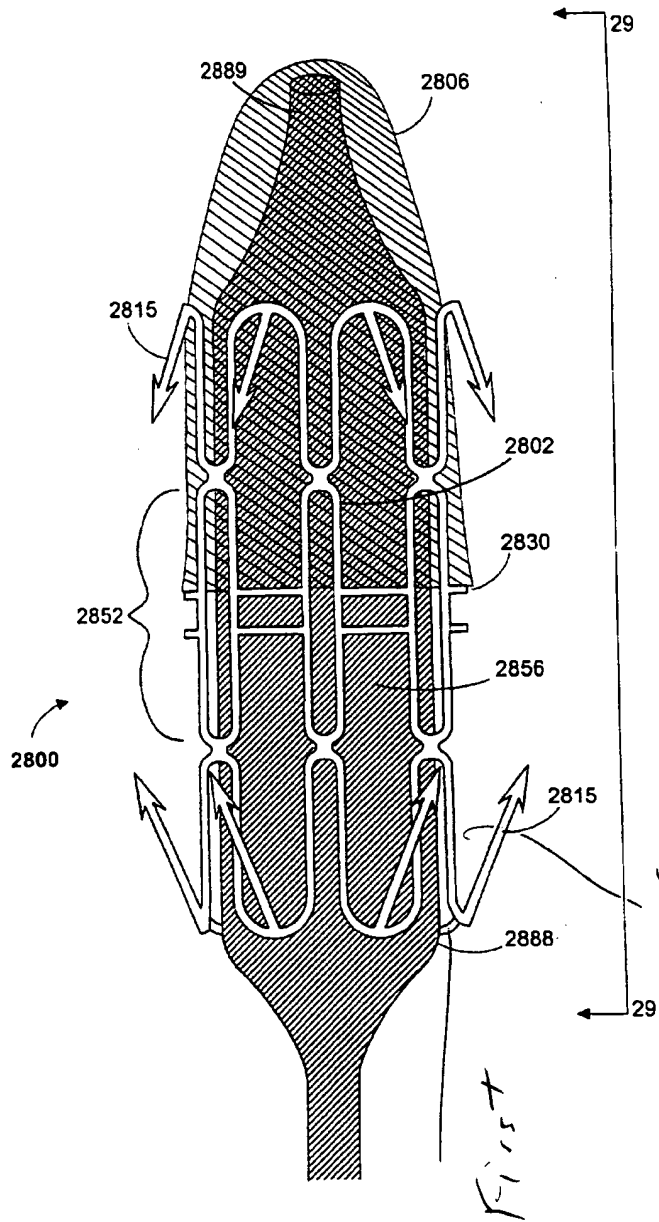


FIG. 28

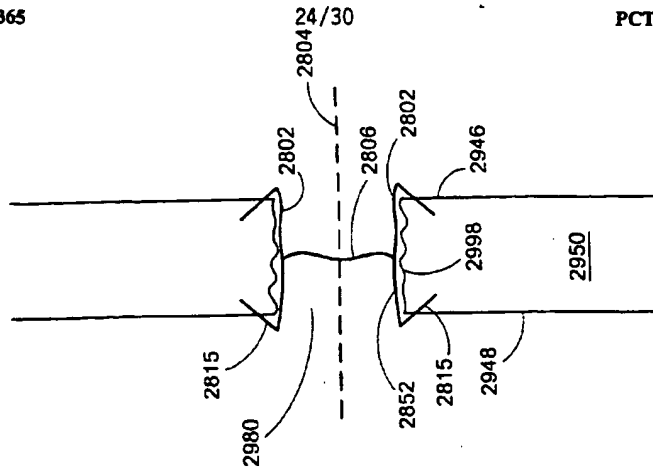


FIG. 29

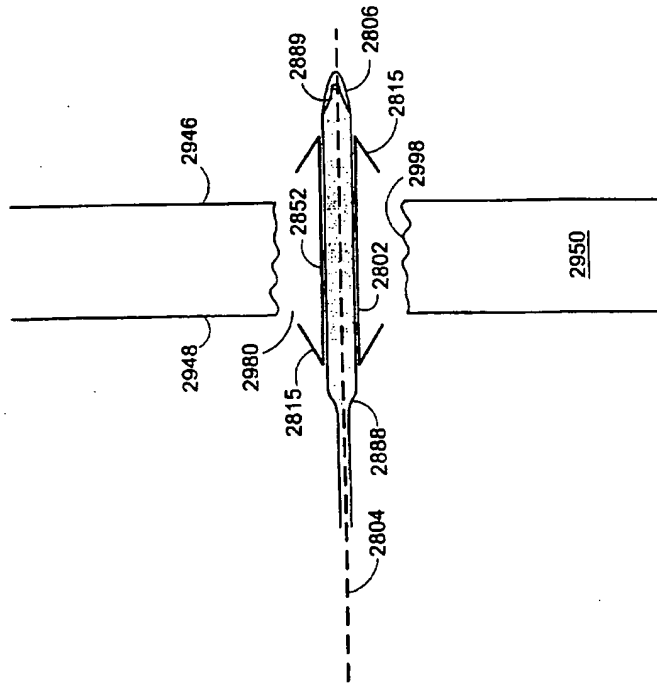


FIG. 30

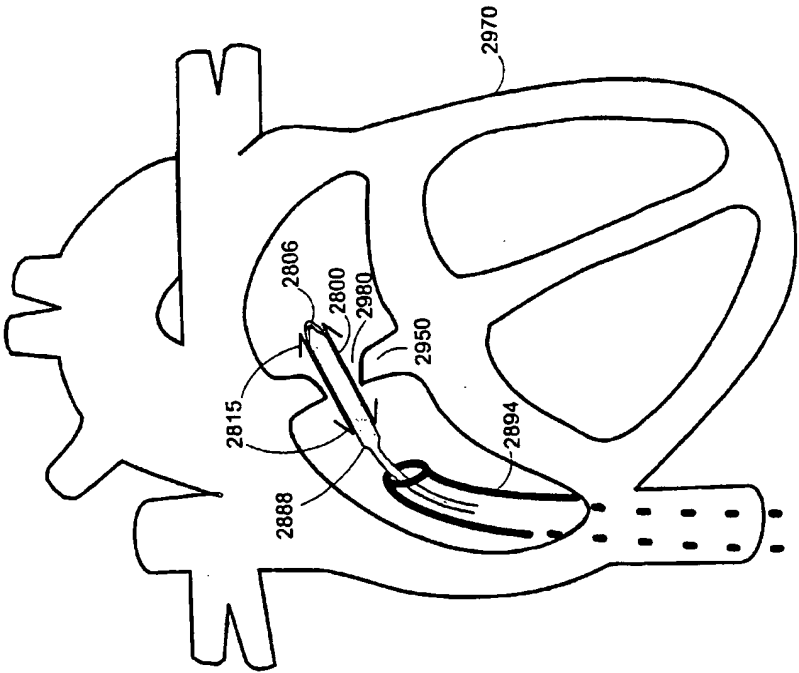


FIG. 31

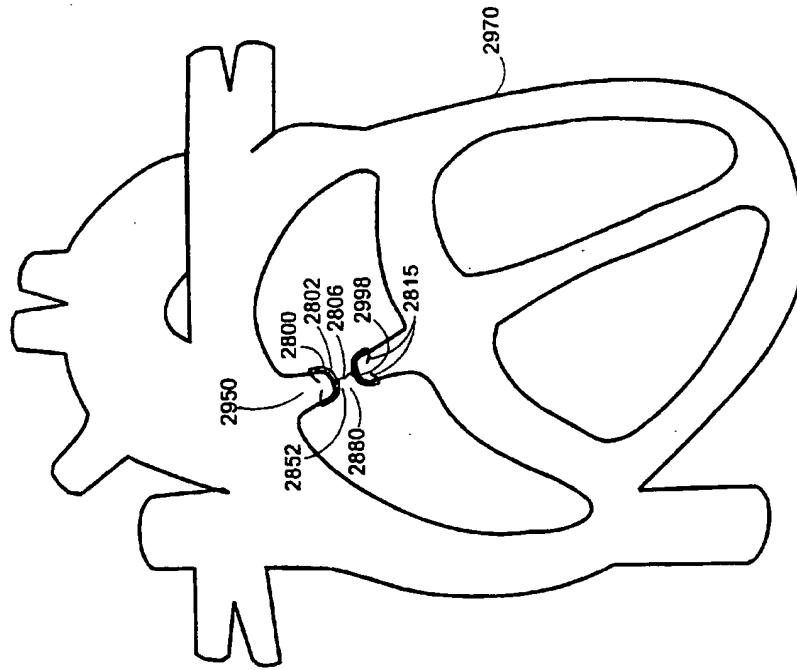


FIG. 32

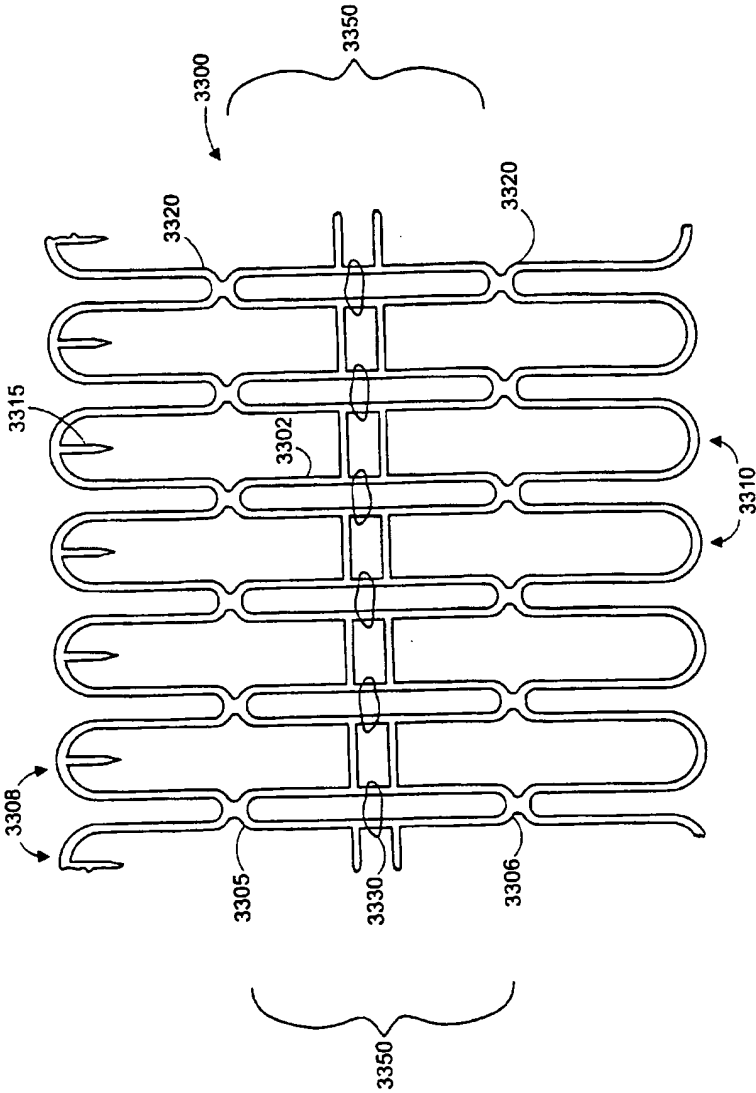


FIG. 33

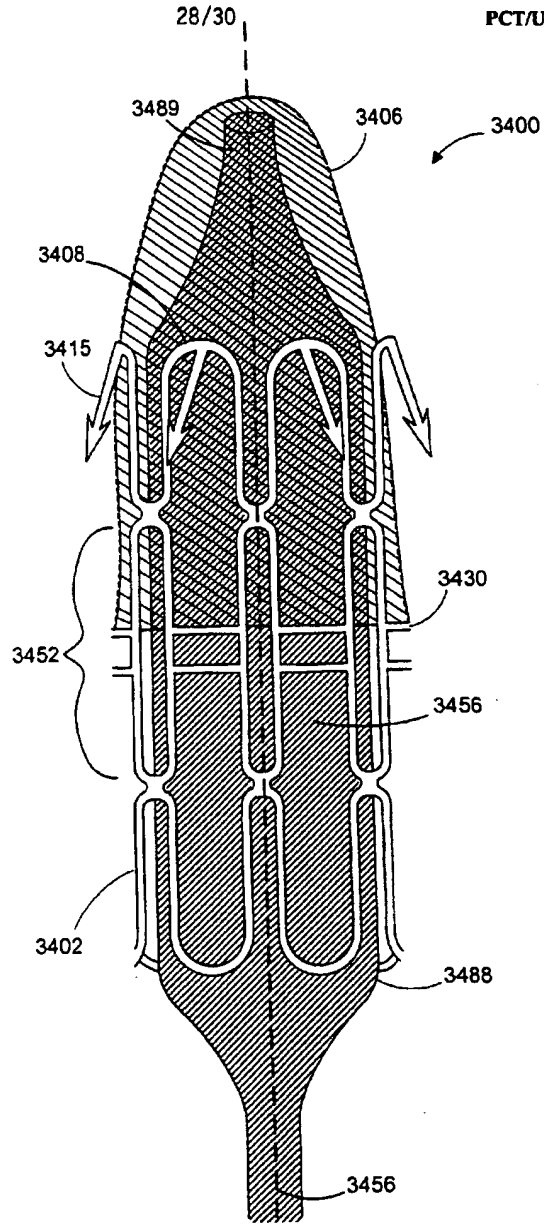


FIG. 34

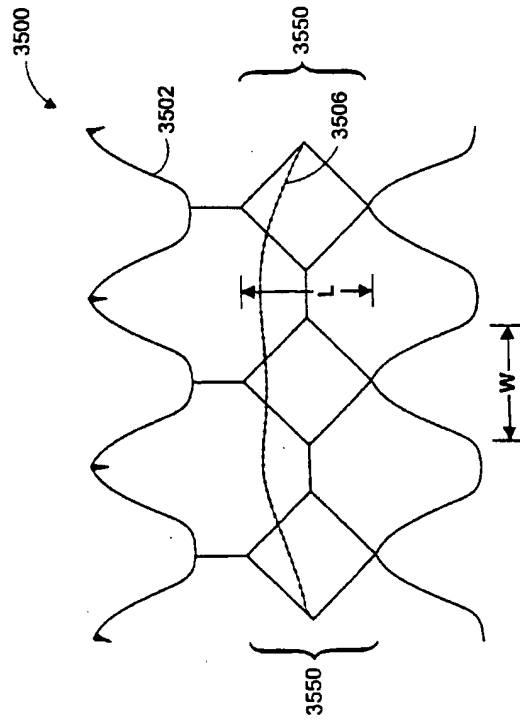


FIG. 35

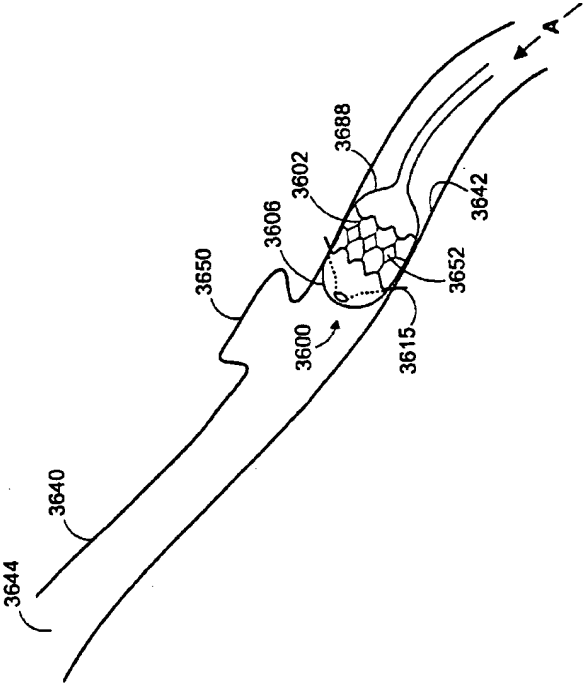


FIG. 36

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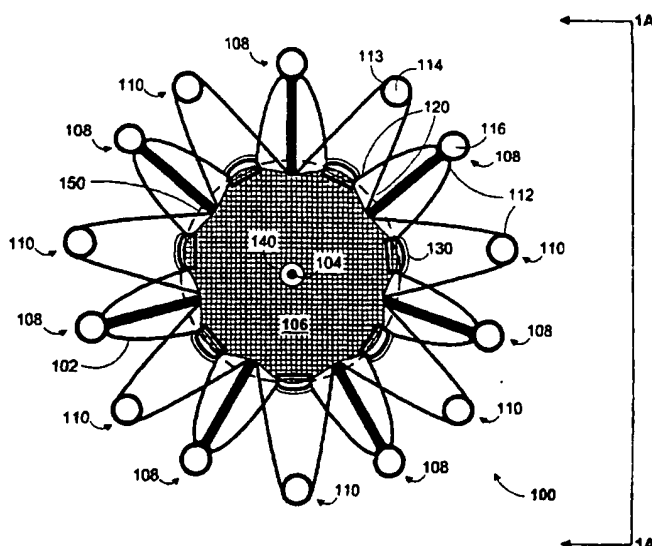
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- (74) Agents: **JACKSON, Robert, R.** et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).
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— With international search report.
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[Continued on next page]

(54) Title: **SEPTAL DEFECT CLOSURE DEVICE**



(57) Abstract: Plugs and methods for plugging septal defects and blood vessels are provided. Plugs are delivered via catheter to a septal defect or a location where it is desired to occlude blood flow in a blood vessel. The plugs are positioned and expanded at the treatment site. The expansion of the plugs can be accomplished passively by using a heat-treated elastic frame or actively by using a balloon to deform a plastically-deforming frame. Plugging structures mounted to the frame span the defect or lumen and prevent blood flow. The plugs described herein have small profiles, and are more reliable than preceding intraluminal transcatheter methods.

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8 March 2001

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